



Insulin Pump & CGM System



Owner's booklet.

Get to know your system.

dexcomG4™
CONTINUOUS GLUCOSE MONITORING

Welcome and Congratulations

Thanks for choosing the Animas® Vibe™ System. Your Animas® Vibe™ System can play an integral part in the blood glucose management and continuous insulin delivery regimen that you have established with your health care professional.

Your Animas® Vibe™ System provides both continuous insulin delivery and continuous glucose monitoring (CGM) when used in conjunction with Dexcom® CGM components.

Your Animas® Vibe™ Insulin Pump provides continuous insulin delivery to help you maintain your blood glucose targets as recommended by your health care professional. It delivers insulin in two ways:

1) continuous “basal” insulin delivery and 2) “bolus” insulin delivery to cover foods eaten and/or reduce a high blood glucose level.

This Owner’s Booklet will provide you with a thorough understanding of your Animas® Vibe™ System and how to get the most from it. The Owner’s Booklet is designed to provide the information you are looking for when you need it, and is organized in an easy-to-find style that places the information at your fingertips. Additional copies of this Owner’s Booklet can be viewed or downloaded by visiting www.Animas.com. The website also provides information about educational programs in your area, frequently asked questions and answers, tips and practice skills for diabetes management, and other valuable tools.

Your Animas® Vibe™ Insulin Pump can be used with or without Dexcom® CGM components. The Owner’s Booklet is set up in Sections, so that you can first learn about using your pump as a stand alone device (Section I), and then learn about using your pump with Dexcom® CGM (Section II).

Of course you may still have questions. If you do, Customer Support or your local Animas distributor will be happy to answer your call. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187). You can also obtain information at www.Animas.com.

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BEFORE YOU BEGIN

Check with your health care professional regarding your individual training needs. **Do Not** attempt to connect to your pump before you have been trained on your pump.

As part of your training, your health care professional will assist you in making the appropriate selections for your insulin pump and continuous glucose monitoring (CGM) settings. Your insulin pump must be programmed for your own personal use as your insulin pump settings impact the calculations for insulin delivery. Be comfortable with using your pump for insulin delivery before you begin using the continuous glucose monitoring (CGM) features on your pump. See the appropriate chapters in *Section I*, pages 1-84 for the steps on setting up and using your insulin pump.

The following insulins have been tested by Animas® and found to be safe for use in the insulin cartridge of the pump: Humalog®, Novo Rapid®, NovoLog®, and Apidra®. Before using a different insulin with this pump, check the insulin drug label and your health care status to make sure it can be used with your pump.

Insulin pump therapy is recommended for people with diabetes who are willing to:

- Test their blood glucose levels four to six times per day or as recommended by their health care team.
- Demonstrate adequate carbohydrate counting skills.
- Maintain good diabetes self-care skills.
- See their health care professional regularly.

and:

- Have adequate vision and hearing to respond to pump alerts, warnings, and alarms.

You should carefully read this Owner's Booklet and any inserts that come with your Animas® Vibe™ System. These include an insert for:

- Animas® Vibe™ System Quick Reference Guide
- Dexcom® CGM Quick Start Guide
- Dexcom® CGM Transmitter
- Dexcom® CGM Sensor

While reading this Owner's Booklet, please note the following:

- Display screens throughout the Owner's Booklet are examples only. They should not be considered suggestions for individual programming and may not be representative of current health states.
- The Animas® Vibe™ Insulin Pump uses a color display screen but display screens throughout the Owner's Booklet are always shown in black and white.
- “Blood Glucose” is often abbreviated as BG in both instructional copy as well as in example display screens.
- “Continuous Glucose Monitoring” is often abbreviated as CGM in both instructional copy as well as in example display screens.
- Your Animas® Vibe™ System consists of an Animas® Vibe™ Insulin Pump, a Dexcom G4™ Transmitter (Dexmitter™), and a Dexcom G4™ Sensor (Dexsensor™). Your Animas® Vibe™ Insulin Pump will often be referred to as simply “your pump”. Your Dexcom G4™ Transmitter will often be referred to as “your Transmitter”. Your Dexcom G4™ Sensor will often be referred to as “your Sensor”. Together, your Dexcom G4™ Transmitter and Sensor will often be referred to as “your Dexcom® CGM” or “your CGM”.

Take special note of Warnings, Cautions, Precautions, and Safety Information throughout this Owner's Booklet, which are identified with .

Intended Use

The Animas® Vibe™ Insulin Pump and Dexcom® CGM System (Animas® Vibe™ System) is indicated for continuous subcutaneous infusion of insulin for the management of insulin-requiring diabetes. The Animas® Vibe™ System is also a glucose-monitoring device indicated for detecting trends and tracking patterns in adults (**age 18 and older**) with diabetes. The Animas® Vibe™ System is intended for use by patients at home and in health care facilities.

The Animas® Vibe™ System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Animas® Vibe™ System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom® CGM results should be based on the trends and patterns seen with several sequential readings over time.

⚠ Warnings, Precautions and Important Safety Information about your Animas® Vibe™ System

Read the entire Section I and Section II of this Owner's Booklet before using your Animas® Vibe™ System. If you do not understand something or have any questions, ask your health care team. Warnings, Precautions, Cautions, Contraindications and other important Safety information about your Animas® Vibe™ System follows below. Be sure to read the information carefully.

⚠ WARNINGS:

- Check with your health care provider regarding your individual training needs. Do Not attempt to connect to your pump before you have been trained on your pump.
- Incorrect use of your pump, failure to follow the instructions in this Owner's Booklet or improper/inadequate self-care and troubleshooting techniques can lead to death or serious injury. If you do not understand something or have questions, ask your health care team or call Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
- Your pump is designed to deliver insulin reliably, but because your pump uses only rapid-acting insulin, you will not have long-acting insulin in your body. To avoid the risk of diabetic ketoacidosis (DKA) or very high BG, you must be prepared to give yourself an injection of insulin if delivery is interrupted for any reason.
- Your pump is designed and calibrated to deliver U100 insulin. Use of any insulin with lesser or greater concentration can result in serious injury or death.
- Never start the Prime/Rewind sequence on your pump while the infusion set is connected to your body. The Prime/Rewind sequence includes steps for rewinding the pump motor, loading an insulin cartridge and tightening the cartridge cap, and priming the infusion set tubing. Failure to disconnect your infusion set from your body before performing these steps can result in over delivery of insulin, and possible injury or death. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycemia.
- You must take a fingerstick test with your BG meter and use that BG value to make any insulin or treatment decisions. Insulin dosing decisions should not be based solely on results from the CGM.
- Your pump and pump accessories include small component pieces that could pose a choking hazard for small children.

⚠ Radiology Equipment

Your pump has been designed to operate in the presence of common sources of electrostatic and electromagnetic interference, such as store security systems. However, like all portable electronic devices, your pump should not be exposed to very strong electromagnetic fields, such as in Magnetic Resonance Imaging (MRI), RF welders or magnets used to lift automobiles. Very strong magnetic fields, such as in an MRI, can re-magnetize the portion of the motor that regulates insulin delivery. **If you plan to undergo an MRI, remove your pump and CGM Transmitter/Sensor beforehand and then keep them outside the room during the procedure.**

⚠ Guidelines Involving Use of the Animas® Vibe™ System During Medical Procedures

⚠ CAUTION: Certain medical procedures involve the use of energy fields (e.g., ionizing radiation, magnetic radiation) that can damage the Animas® Vibe™ System. Device users must **NEVER** expose the pump, CGM Transmitter/Sensor and certain infusion sets to these types of energy fields. **ALWAYS** remove the pump and CGM Transmitter/Sensor before entering the room where one of these procedures will be performed.

Medical Procedure	Device User (Patient or HCP administering the procedure)
CARDIAC CATHETERIZATION	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
COLONOSCOPY	• Pump, infusion set and CGM Transmitter/Sensor can remain on/in.
CT SCANS	• Do Not bring pump into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
EKG	• Pump, infusion set and CGM Transmitter/Sensor can remain on/in
ELECTRO-CAUTERY	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
LASER SURGERY	• Pump, infusion set and CGM Transmitter/Sensor can remain on/in
MRI	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
NUCLEAR STRESS TEST (myocardial perfusion imaging)	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.

Medical Procedure	Device User (Patient or HCP administering the procedure)
PACEMAKER/AICD Reprogramming	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
THERAPEUTIC RADIATION/ ONCOLOGY (cancer treatment radiation)	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
ULTRASOUND	• Pump, infusion set and CGM Transmitter/Sensor can remain on/in
X-RAY, BODY FLUOROSCOPY (chest, neck, abdomen, torso, etc.)	• Do Not bring pump into the same room where the procedure is being performed, unless a lead apron that completely covers pump is worn during the procedure. The person administering the procedure (if they are wearing a pump) must proceed to a designated safety area during the procedure. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
X-RAY, BONE DENSITOMETRY	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed, unless a lead apron that completely covers pump and CGM Transmitter is worn during the procedure. The person administering the procedure (if they are wearing a pump or CGM Transmitter) must proceed to a designated safety area during the procedure. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
X-RAY, DENTAL	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.
X-RAY, MAMMOGRAM	• Do Not bring pump or CGM Transmitter/Sensor into the same room where the procedure is being performed. • Teflon/plastic infusion set can remain in. Other types of infusion sets must be removed.

⚠ PRECAUTIONS

- Your pump is a sealed device that should be opened **ONLY** by the manufacturer. If your pump seal is broken by anyone other than an authorized Animas® factory technician, the warranty is voided and your pump is no longer waterproof. If the back label on your pump is removed or damaged, the warranty is voided and your pump is no longer waterproof.
- When using your pump, if the pump is placed at a vertically higher position than the infusion site, a small amount of additional insulin infusion may occur. To minimize this condition and maintain pump delivery accuracy, the vertical distance between your pump and the infusion site should be no more than 30 centimeters (12 inches). If your pump is placed at a vertically lower position than the infusion site, this condition is eliminated.
- Occasionally check the infusion site for proper placement and leaks. Improperly placed infusion sites or leaks around the infusion site can result in under infusion.
- Occasionally check the infusion set tubing for any damage, leaks or kinks while using your pump. Damaged, leaking or kinked tubing may restrict or stop insulin delivery and result in under infusion.
- Only use Animas® 2.0 mL Cartridges (200 unit/2ml) and infusion sets with a standard Luer connector. Efficacy of pump cannot be guaranteed if cartridges other than those manufactured by Animas Corporation are used or if cartridges are used more than once.
- Always dispose of used cartridges and infusion sets following the regulations in your community. Failure to follow these guidelines may pose health hazards.
- Prior to replacing the battery cap, make sure the o-ring fits securely and is not damaged. A damaged o-ring may impact the battery contact and/or the waterproof feature of your pump. See *Chapter 3 in Section I*, pages 9-20.
- Prior to inserting a cartridge into your pump, check the o-rings on the cartridge to be sure they are not damaged. Damaged cartridge o-rings can result in under or over delivery of insulin.
- Occasionally check the vents to be sure they are clear of debris. See *Chapter 1 in Section III*, pages 141-144.
- Occasionally check that your pump personal settings are correct.
- Occasionally check to make sure your pump emits audible tones that are easily detectable and that the vibrate feature is working correctly. For example, audible tones should be heard and the vibration pulse felt every time you replace the battery.
- If using the download feature, keep the communication window free of obstructions and refer to the *Instructions for Use* included with the wireless download cable. Visit www.diasend.com/animas for information on the Diasend® Web-based Diabetes Management System that you can use to track, review and analyze pump data on your computer. You can also contact Customer Support or your local Animas distributor for information on Diasend® Diabetes Management Software and wireless download cable. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
- Choose an area at least 7.6 centimeters (3 inches) away from your infusion site or where you plan to inject insulin, to insert the CGM Sensor. Avoid skin sites with tattoos, or areas with rough patches or scarring from your pump or insulin injections.

⚠ PRECAUTIONS *(continued)*

- Your pump uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.
- Your pump is designed only for Continuous Subcutaneous Insulin Infusion (CSII). It is not intended for use with any other delivery substance.
- Consult your health care team before using your pump to determine which programming features are appropriate for you. Some features require a greater knowledge of insulin pumping and advanced self-care skills. Additionally, some advanced programming features require that testing and fine-tuning of basic settings be completed in order to achieve the best possible results. Your health care team will give you specific training on programming and using your pump.
- Use of Extended Bolus, Combo Bolus, ezCarb (carb calculator), Insulin on Board (IOB) and ezBG (BG correction calculator) all require input from your health care team. Do Not attempt to use these features until you have specific information for your treatment plan and have had specific training on each programming feature.
- Only your health care team can determine your Insulin to Carbohydrate (I:C) ratios, Insulin Sensitivity Factors (ISFs), BG Target ranges and duration of Insulin on Board (IOB).
- Treatment decisions should not be based on CGM results. You must confirm your CGM results with results from a BG meter before making dosing decisions.
- Basal rates that are too high or too low can adversely affect BG levels. Work with your health care team to fine-tune basal rates.
- The way your body uses insulin can be affected by many things. Contact your health care team about lifestyle changes such as starting/stopping your exercise program or significant weight loss/gain. Your basal rates may need to be modified.
- Do Not stop using your pump if you are ill unless instructed to do so by your health care provider. Even when you are sick, your body still needs insulin. See Chapter 4 in Section III, pages 157-158.
- When you first start using the Audio Bolus feature, always look at the display screen to confirm correct programming until you are comfortable using this feature.
- Animas Corporation recommends that you have someone around you (family, friends, etc.) who understands diabetes and pump therapy, so in the event of an emergency, they can help you. Be sure they are familiar with any information given to you by your health care team.

⚠ Amusement Parks

Very powerful electromagnets are sometimes used on “free-fall” amusement park rides. Pumps should be removed and not taken on these “free-fall” types of rides.

High gravity forces can be experienced when riding on some roller-coasters. It is recommended that you disconnect (NOT suspend) your pump while on roller-coaster rides.

⚠ Aircraft without Cabin Pressurization

If flying in aircraft without cabin pressurization or flying in aircraft used for aerobatics or combat simulation (pressurized or not), disconnect (NOT suspend) pump.

⚠ PRECAUTIONS *(continued)*• **Before Bedtime**

- Plan infusion set changes at meals or one to two hours before bedtime. If a change is needed at bedtime, then check BG in one to two hours. Always check BG one to two hours after infusion set change.
- Always check that your cartridge has enough insulin to last through the night before going to bed. Unless otherwise recommended by your health care team, set the volume to high for all warnings and alarms before going to sleep.
- Always remove all air bubbles from cartridge and tubing before beginning insulin delivery. Air bubbles can compromise accuracy of delivery. Refer to the Instructions for Use included with your cartridge packaging.
- Interference with your pump insulin delivery by cell phones can occur if worn in close proximity. It is recommended that you wear your pump and cell phone at least 15.2 centimeters (6 inches) apart. Cell phones will not interfere with CGM functions on your pump.
- If you return your pump for service and a replacement pump is sent, Do Not use the replacement pump until all the settings specific to your treatment plan have been programmed.
- If you drop your pump or it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and clear, that the cartridge cap, battery cap and infusion set are properly in place. Check for leaks around the cartridge by wrapping a piece of tissue around the connection area. Cracks, chips or damage to your pump may impact the battery contact and/or the waterproof feature of your pump. Call Customer Support or your local Animas distributor if you identify or suspect your pump has been damaged. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187). They will help determine if your pump should be replaced. You can also obtain information at www.Animas.com.
- Your pump is designed to operate in conditions where temperatures are between 5° C (40° F) and 40° C (104° F). If your pump is exposed to temperatures outside these parameters, extra care should be taken to protect it from extreme temperatures.
- To avoid risk of explosion, Do Not use your pump in the presence of explosive gases.
- Your pump is designed to achieve optimum performance and battery life with an Energizer® Lithium Ultimate AA battery (1.5V). Rechargeable batteries and Carbon-Zinc batteries do not have the necessary characteristics to power your pump and should not be used. Some AA lithium batteries are available with other voltages such as 3.6V or 4.0V. Do Not use these batteries. Use of anything other than a 1.5V battery could permanently damage your pump and voids its warranty.
- Do Not use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your pump. Never put your pump in the dishwasher or use very hot water to clean it.
- Never use a hair dryer, microwave oven or baking oven to dry your pump. Use a soft towel.

⚠ CONTRAINDICATIONS:

- The CGM Sensor and Transmitter must be removed prior to Magnetic Resonance Imaging (MRI).
- Use of acetaminophen-containing medications while the CGM Sensor is inserted may affect the performance of the CGM.

⚠ WARNINGS:

- The CGM is not designed to replace a blood glucose meter. The CGM must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the CGM. You must confirm with a blood glucose meter before making therapeutic adjustments.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the CGM results.
- You should update the CGM's calibration every 12 hours at a minimum. The performance of the CGM when calibrated less frequently than every 12 hours has not been studied.
- CGM Sensors may fracture on rare occasions. If a CGM Sensor breaks and no portion of it is visible above the skin, Do Not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the injection site. If you experience a broken CGM Sensor, report this to Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
- CGM is Not Approved For Use in children or adolescents, pregnant women or persons on dialysis.
- The safety and effectiveness of the CGM has not been evaluated for Sensor Probe insertion sites other than the abdomen.
- Your Animas® Vibe™ System will not automatically make insulin adjustments based on CGM readings. You must take a fingerstick test with your blood glucose meter and use that blood glucose value to make any insulin or treatment decisions. Insulin dosing decisions should not be based solely on results from the CGM.

⚠ PRECAUTIONS:

- **Always wash hands with soap and water before opening the CGM Sensor package. After opening the package, avoid touching the adhesive area.**
- **Before inserting the CGM Sensor, always clean the skin at the insertion location with a topical antimicrobial solution, such as isopropyl alcohol. Do Not apply the CGM Sensor until the cleaned area is dry.**
- **Establish a rotation schedule for choosing each new CGM Sensor location. Avoid locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.**
- **Avoid injecting insulin or placing an insulin pump infusion set within 7.6 centimeters (3 inches) of a CGM Sensor.**
- **The CGM Sensor is sterile in its unopened, undamaged package. Do Not use any CGM Sensor if its sterile package has been previously damaged or opened.**
- **When entering fingerstick blood glucose values for CGM calibration, you must enter the exact blood glucose value that your blood glucose meter displays. Enter all fingerstick blood glucose values for CGM calibration within 5 minutes. Entering incorrect fingerstick blood glucose values, or fingerstick values that occurred more than 5 minutes ago, will affect CGM performance.**

All mentions of screen displays, menus, buttons, etc. in Section II refer to the Animas® Vibe™ Insulin Pump unless specifically stated otherwise.

About Radio Frequency (RF) Communication

Your pump has built-in RF capability. RF is a type of wireless communication. Cell phones use RF technology, as do many other devices. RF is how your pump and CGM communicate and share CGM data.

The RF feature on your pump will be deactivated when you first receive it. In order to begin using your pump and CGM together as a system, you must enter the ID number of your CGM Transmitter into your pump.

RF communication between your pump and CGM will work up to a distance of about 3.6 meters (12 feet) and will transmit through clothing. Direct line of sight is not required for RF communication. As long as you have a good RF signal and are within range, you can use your pump to display CGM data. Exposing your pump and CGM to water, and certain objects in between the two devices may interfere with RF communication.

When conditions or distance cause RF communication to be lost or interrupted, you will not be able to use your pump to display CGM data. This also means that data transfer between the two devices will stop temporarily. As soon as the problem is resolved, RF communication will resume. Refer to page 155 for more information on conditions that may cause RF communication problems.

NOTE:

Any changes or modifications to the Animas® Vibe™ System not expressly approved by Animas Corporation or Dexcom, Inc. could void the user's authority to operate the equipment.

Animas® Vibe™ System Kit Contents

Your Animas® Vibe™ System Kit includes your insulin pump and other accessories you will need to begin insulin delivery. Check the contents of your kit to make sure all items are included. If any items are missing call Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

The CGM Sensor and Transmitter and supplies are packaged and provided separately.

Your Animas® Vibe™ System Kit includes:



- a.** Animas® Vibe™ Insulin Pump
 - b.** One Energizer® Lithium Ultimate AA battery (1.5V) for your pump
 - c.** Low Profile Clip
 - d.** Owner's Booklet*
 - e.** Quick Reference Guide*
 - f.** Orientation DVD*
- * not pictured

Explanation of symbols

Shown below are symbols you will find on your Animas® Vibe™ Insulin Pump and its packaging.

On your pump kit packaging:



Do Not Reuse



Pressure Limitations



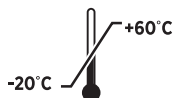
Fragile



Relative Humidity Limitations



Keep Dry



Temperature Limitations



Caution (Consult Owner's Booklet)

On the front of your pump:



Up Arrow button



Down Arrow button



OK button



On the top of your pump:



Contrast button/CGM shortcut

On the back of your pump:



Serial Number



Manufacturer



Date of Manufacture



Protected against water submersion
– Pump tested to 3.6 meters (12 feet)
for 24 hours



Shock Protection Type BF Medical
Equipment



Consult Owner's Booklet



Do Not wear or operate around MRI
devices. Remove and leave outside
MRI room before entering.



Catalog Number

BEFORE YOU BEGIN

The following symbols may be found on the CGM Sensor and Transmitter package labels. These symbols tell you about the proper and safe use of the CGM. This table shows what each symbol means.

	"Use by" Date		Protected against water jets
	Caution (Consult Owner's Booklet)		Protected against water submersion – CGM tested to 2.4 Meters (8 feet) for 24 hours
	Date of Manufacture		Consult Owner's Booklet
	Do Not Reuse		Manufacturer
	Serial Number		Humidity Limitation
	Sterilized by Radiation		Shock Protection Type B Applied Part
	Do Not Use if Package is Damaged		
	Lot Number		
	Catalog Number		
	Two-sided Temperature		

Supply Reordering

You can place orders for cartridges, infusion sets, skin prep, batteries, replacement battery caps, and many pump accessories by calling Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

To place orders for CGM supplies, contact Customer Support or your local Animas distributor (see page 187).

Emergency Kit

Keep an emergency kit with you at all times to make sure you have necessary supplies.

This kit should include but is not limited to:

- Quick-acting glucose tablets or gel
- BG monitoring supplies including meter, test strips, lancing device, lancets, meter batteries
- Blood or urine ketone testing supplies
- Rapid-acting and other insulin as recommended by your health care team
- Extra infusion sets and Animas® 2.0 mL Cartridges (200 unit/2ml)
- Dressing and adhesive, if used
- An extra Energizer® Lithium Ultimate AA battery for your pump
- An extra pump battery cap
- An extra pump cartridge cap
- Glucagon Emergency Kit®
- Emergency contact phone numbers
- A backup plan for obtaining and delivering insulin when you are unable to use your pump

Be sure to inform a family member, co-worker, and/or friend where this emergency kit is kept.

Section I

Animas® Vibe™ Insulin Pump



CHAPTER 1 - INSULIN PUMP OVERVIEW

Section I of this Owner's Booklet contains information about how to use, program, and maintain your new pump. It is important to read it carefully. Even if you are an experienced pumper, keep your Owner's Booklet handy for reference. Any reference to CGM refers to the optional Dexcom® CGM that is reviewed in Section II.

You have begun a new way of life with your Animas® Vibe™ System.

Your choice to begin pump therapy is a sign that you are committed to taking excellent care of yourself. Your pump has been specially designed to help you manage your diabetes, using sophisticated safety systems.

Your pump is used for insulin therapy to help maintain your blood glucose (BG) targets as recommended by your health care team. You program it to deliver two ways: 1) a continuous, 24-hour “basal” rate and 2) “bolus” insulin deliveries to accommodate for immediate doses to cover foods eaten and high BG. It is important to remember that successful pump therapy is a partnership of advanced technology and responsible self-care.

Please take a moment to look at the back of your pump and write down the serial number.

My pump serial number is: _____



Technical Help

If there is anything you do not understand in the Owner's Booklet or if you have a question or need assistance with your pump, contact Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

We understand that you may have questions and concerns when using a new product. Please do not hesitate to call for assistance!

If you are having problems with your diabetes management, please contact your health care team.

Important Note

Do Not Remove the Factory-Installed Plastic Display Lens Protection Film.

Your pump now comes with a new factory-installed transparent plastic lens protection film covering the display lens. This protective film is highly durable and is designed to protect your pump display lens from incidental damage. **Do Not attempt to remove this film. This protective film must remain in place at all times to fully protect your pump display lens from scratches and other cosmetic damage.** This film will not protect your pump display lens from extreme abuse.

Should the pre-installed lens protection film become damaged or separate from the display, the film should be replaced. Replacement films can be purchased by calling Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

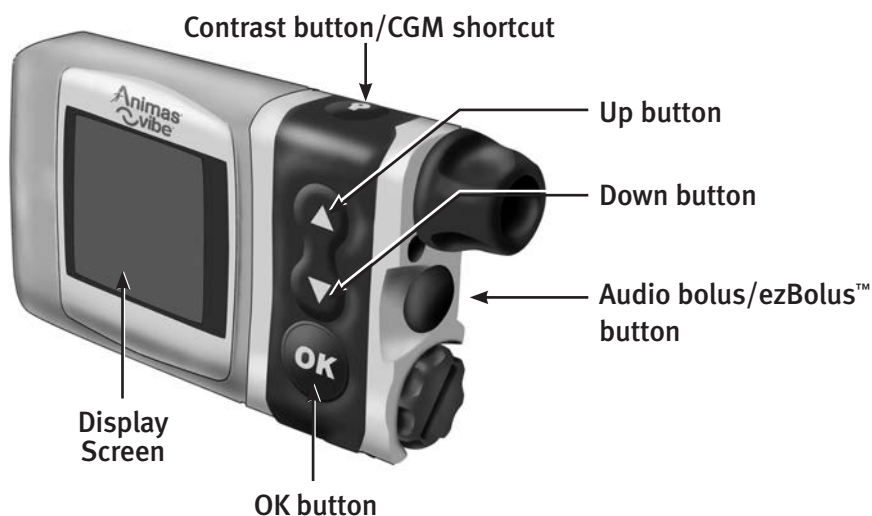
Please note that the Animas® Vibe™ Insulin Pump limited warranty does not cover damage resulting from normal wear and tear, accidents, negligence or misuse, and abuse, including scratched display lenses. We urge you to protect your pump screen from damage and use a lens protection film at all times.

CHAPTER 2 - INTRODUCTION TO YOUR ANIMAS® VIBE™ INSULIN PUMP

An insulin pump is a tool to allow you to better manage your diabetes. When connected to a properly-inserted infusion set, your pump delivers insulin at a continuous level (basal rate), 24 hours a day. You program delivery of an immediate dose (bolus) of insulin to cover food eaten or to correct high BG.

Your pump is engineered and manufactured to the highest standards of quality.

Get to Know Your Animas® Vibe™ Insulin Pump



Main Function Buttons

There are 4 buttons for main programming functions. The ▲ and ▼ buttons allow you to move through screen selections and to scroll up and down to enter values such as a bolus amount. The OK button allows you to select an item or activate a function. The Audio bolus/ezBolus™ button allows you to program a bolus using audible tones (or vibrate pulses) to confirm programming and delivery.

Programming Basics

- Use the ▲/▼ buttons to scroll to the desired selection and then press the OK button to select. If the cursor is flashing, it means your pump is in Edit Mode and by scrolling with the ▲/▼ buttons, you can edit the flashing field.
- Once you have finished editing, press the OK button to confirm your entry and to exit the Edit Mode.
- If your pump display turns off before you have had a chance to confirm your entry, that entry will not be saved. Be sure to check your edits/entries the next time you turn your pump display on.

Display Screen

All programming, operations, warnings and alarms are shown on the display screen.

Contrast Button/CGM Shortcut

Pressing this button adjusts the contrast of your display. There are three contrast levels: Dim, Default and Bright. To preserve battery life, your pump display will Auto-dim when a button is not pressed for half the time your display time-out is set. While in **Auto-dim** mode, you can restore the default contrast level you have set by pressing the  button on top of your pump. Pressing a function button while in Auto-dim mode will restore the default contrast level as well as perform the function of the key. To adjust contrast during a Call Service alarm, you must use the  button. See *Chapter 9 in Section I*, pages 43-56.

While the pump is in sleep mode, pressing the  button will awaken the pump to one of the CGM Trend graphs or the CGM Data screen. See *Chapter 6 in Section II*, pages 109-118.

NOTE:

- When viewing your pump display in bright sunlight, it is recommended you shade the screen or move to a shady area for best visibility.
- If your pump goes to sleep and an error has not been cleared, pressing the  button will awaken the pump to the error screen. This will continue until the error condition has been cleared.

Audio Bolus/ezBolus™

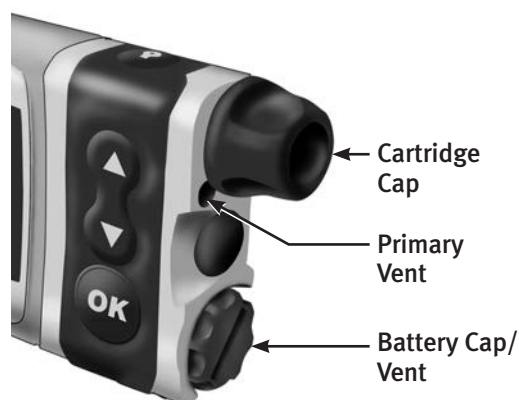
This button allows you to program a bolus without looking at your pump, by using audible tones (or vibrate pulses) to confirm programming and delivery. If you choose not to activate the Audio Bolus feature, this button provides a shortcut to the Normal Bolus screen.

NOTE: When you first use the Audio Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with using audio or vibration feedback to program a bolus. See *Chapter 9 in Section I*, pages 43-56.

⚠ WARNING: Removal of the Audio Bolus/ezBolus™ button could damage the pump. In addition, it could affect the integrity of the pump and compromise the pump's waterproof capabilities.

Battery Cap/Vent

This cap unscrews easily with a coin to replace and secure your battery. There is an o-ring around the cap, which prevents water from entering the pump. The battery cap also is equipped with a built-in vent to allow air to enter your pump to maintain pressurization but prevent water from entering. Be careful not to over tighten the battery cap. See *Chapter 3* in *Section I*, pages 9-20.



Primary Vent

This vent is part of the redundant vent safety system, which allows air inside your pump to maintain equalized pressure but prevents water from getting inside.

⚠ WARNING: Under no circumstances should you introduce any kind of sharp object into the vent openings. Doing so will compromise your pump's waterproof capabilities. If at any time you suspect the vent openings are clogged, replace the battery cap.

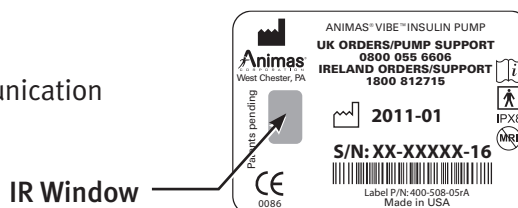
Cartridge Compartment Cap

This cap secures your cartridge and infusion set in your pump.

⚠ WARNING: Never tighten the cartridge cap when your infusion set is attached to your body. Tightening the cartridge cap while your infusion set is attached to your body may result in unwanted insulin delivery, which can result in serious injury or death.

IR Window for Download

The IR window is framed in blue. This is the infrared communication window used for downloading your pump data.



Sounds

Your pump allows you to customize the volume level or use the vibrate function to notify you of warnings and alarms and to confirm certain insulin deliveries. In addition, you have the option to set CGM-related alarms and alerts in the CGM setup Menu (see *Chapter 2* in *Section II*, pages 87-94).

Tamper Resistant (Locked) Feature

You can use the tamper resistant feature to prevent accidental button pressing. Simply wake up your pump and press and hold the ▲ and ▼ buttons at the same time until the screen reads “(LOCKED) Press & hold both arrow buttons to unlock”. This locks your pump buttons. To unlock your pump, wake up your pump so the screen reads “(LOCKED) Press & hold both arrow buttons to unlock” and press and hold the ▲ and ▼ buttons at the same time until the screen display wakes up.

Basic Display Screens

Verify Screen

When you insert a battery, this is the first screen you see after the hourglass appears on the display. From here you should verify the settings for time, date, language and battery type. With “Confirm” highlighted, press **OK** to confirm the settings and go to the Home screen.

VERIFY	
	2:27PM
Mode	12 Hr
Month	Jan
Day	7
Year	2010
ENGLISH	
Battery = Lith	
Confirm	

NOTE:

- If you were in the middle of a CGM session when you inserted a battery, the Verify screen will continue to appear for about 8 seconds after pressing **OK** to confirm. The CGM session will resume once the Home screen appears.
- If you do not confirm the settings on the VERIFY screen, you will be notified with an alarm beep sequence on your pump. If not confirmed, the pump will play 4 long tones/vib every 3 minutes until the screen is confirmed.
- It is important to have the correct (current) date and time set in your pump. If the pump loses the date and time setting due to the battery being removed for an extended period, you will not be able to go to the Home Screen (see below) until you edit and confirm the settings on the Verify Screen.

Home Screen

Once you have your pump set up, the Home screen is the first screen that is displayed when you “wake up” your pump. Press the ▲, ▼ or **OK** button to wake up your pump. (The Home screen shows the time of day, an approximate battery life indicator, if you have an extended bolus or temp basal currently active, current basal rate, and how much insulin remains in your cartridge.) You can access the Main Menu from here or you can take a shortcut to the Status menu. The battery life indicator is shaded to show approximate battery life remaining.

2:27PM	
	
Basal Rate	
0.025U/Hr	
Insulin: 105U	
Status	Menu

Battery life indicator

-  **NOTE:** Battery life varies by type of battery, storage conditions, and how long the battery has been in use. Expect actual battery life to be less than what is shown by the battery life indicator if you access pump features on a regular basis. Be prepared to replace the battery whenever the battery icon shows that it is less than completely (shaded) full.
- 
- 
- 

After a set amount of time with no button presses, your pump display screen will “time out” to conserve battery life. When your pump times out, the screen display is blank.

Main Menu Screen

This screen shows all Main Menu options.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

Bolus

This selection takes you to the Normal Bolus screen. If you have activated Advanced Bolus features, the Bolus Menu will be displayed. From the Bolus Menu you can select the bolus type, program and deliver the bolus dose.

CGM

This selection takes you to the CGM Menu screen where you can access all CGM functions available on your pump. In addition, you have the option to set BG limits, alarms, sound levels, etc.

Suspend/Resume

This selection stops all insulin deliveries and Resume restarts basal delivery.

History

This selection allows you to review history of boluses, total daily dose (TDD), alarms, primes, suspend and basal information.

Basal

This selection allows you to access and program your basal rate. This continuous rate maintains your BG between meals. This rate will be determined by your health care team. The default Basal Menu will display one basal program and the Temp Basal option. You can activate additional basal program options with the Setup Advanced menu.

Setup

This selection allows you to personalize the settings and features of your pump, as well as add advanced features to the menu. Your health care team will advise you on which features are best suited for your plan of treatment, as well as train you to achieve the best results.

Prime/Rewind

This selection enables you to properly align the cartridge and piston rod, as well as prime your infusion set tubing and fill your cannula or needle before connecting to your pump.

Status

This selection allows you to quickly see your current/most recent settings and pump deliveries.

CHAPTER 3 - GETTING YOUR PUMP READY

⚠ WARNING: Before proceeding with this chapter, you should have completed your pump training.

To complete this section, you will need the following items:

- Animas® Vibe™ Insulin Pump
- Energizer® Lithium Ultimate AA battery (1.5V)
- Coin
- Infusion set with standard Luer connector
- Animas® 2.0 mL Cartridge (200 unit/2ml)
- Alcohol wipe (to clean top of insulin vial)
- Vial of U100 insulin (rapid-acting) at room temperature (see allowed insulin types, page I)
- Skin prep such as IV Prep™ (to clean and prepare site for infusion set insertion)

⚠ CAUTION: Under no circumstances should you use an alcohol wipe or skin prep to clean your pump. See *Chapter 1 in Section III, pages 141-144.*

Battery Type

Your pump is designed to achieve optimum performance and battery longevity with an Energizer® Lithium Ultimate AA battery (1.5V). Check to be sure you have the correct lithium battery type before inserting the battery.

⚠ CAUTION: It is possible to safely power your pump with a conventional AA alkaline battery (1.5V), but battery life is significantly reduced. Be sure you select the correct Battery Type on the VERIFY screen when you change the battery to ensure accuracy of the Low and Replace Battery Warnings.

If you must use an AA alkaline battery, the following is recommended:

- Energizer® EA91

⚠ WARNING:

- Rechargeable batteries and Carbon-Zinc batteries do not have the necessary characteristics to power your pump and must not be used. Use of these batteries voids your pump warranty.
- Under no circumstances should you attempt to power your pump with a high-energy 3.6V AA Lithium battery. Use of these batteries could permanently damage your pump and voids its warranty.

NOTE: Your pump uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.

Changing the Battery

Each time you change the battery

- Always disconnect from infusion site prior to changing the battery.
- A full rewind and prime sequence is required. See *Priming your Pump and Infusion Set*, pages 16-18 in this chapter.
- The Insulin on Board (IOB) calculation starts over at zero (0.00U).
- The Combo bolus returns to the factory set default duration and split.
- You should review your basal program settings.

⚠ WARNING:

- **Low Battery Warning** means battery life will only last a minimum of 30 minutes.
- **You can remove the pump battery for up to 12 hours. Once you re-insert the battery, the pump will prompt you to enter the time and date. You must reset time and date.**
- **The Replace Battery alarm will stop all CGM functions, and no further CGM readings will be displayed until the battery is replaced (see *Section II*, pages 85-140).**

1. Disconnect from infusion site.
2. Use a coin to unscrew the battery cap with a counter-clockwise motion.
3. Check your battery cap for damage such as cracks or missing threads, and be sure the colored o-ring fits securely and is not torn or damaged.
4. Check the vent hole on the top of the battery cap to be sure it is clear of debris. This vent maintains pressurization while preventing water from entering the compartment.

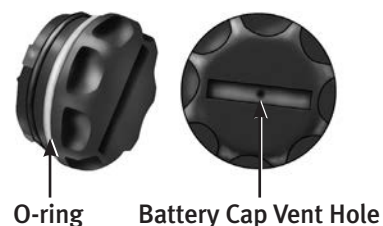
NOTE: The battery cap should be replaced every six months, or sooner if the o-ring or cap is damaged or the vent is clogged. See *Chapter 1* in *Section III*, pages 141-144.

5. Insert the Energizer® Lithium Ultimate AA (1.5V) battery into the battery compartment with the positive (+) end going in first.

6. Replace the cap by turning clockwise until you cannot see the o-ring. Then slowly tighten the cap until flush with pump body.

NOTE: Using excessive force to tighten the battery cap can cause your pump case to crack. Cracks, chips, or damage to your pump may impact the battery contact and/or the waterproof feature of your pump.

7. Each time you change the battery, your pump will run a series of self-tests which will last a few seconds. An all black screen with an hourglass symbol will appear followed by the VERIFY screen. Your pump will give a beep to alert you to verify (or change) the time/date, language and battery type.



8. Check the displayed time/date, battery type and language. If correct, scroll down to highlight “Confirm” and press the **OK** button. The Home screen will be displayed. For more details on changing the time and date, see *Setup – Basics, Setting/Changing Time and Date*, pages 11-12 in this chapter.

NOTE: The time and date must be programmed to confirm the VERIFY screen.

9. To change the battery type, highlight the “Battery” field and press **OK** to activate Edit mode (indicated by flashing cursor).

10. Use the **▲/▼** buttons to change battery type and press **OK** to confirm and exit Edit Mode.

NOTE:

- The correct battery type must be selected in order for your battery life indicator to be accurate. “Lith” = Lithium, “Alkl” = Alkaline.
- It is important to have the correct (current) date and time set in your pump. If the pump loses the date and time setting due to the battery being removed for an extended period, you will not be able to go to the Home Screen until you edit and confirm the settings on the Verify Screen.

11. Scroll to “Confirm” and press **OK**. The Home screen is displayed.

NOTE: Until you have programmed a basal rate, the Alert screen shown here will appear when your pump is awakened. Simply scroll to “Confirm” and press **OK** to move past this Alert screen.

12. Each time you change the battery, a full Prime/Rewind sequence is required (see *Priming your Pump and Infusion Set*, pages 16-18 in this chapter). You do not have to remove your cartridge if the battery change is being done without a cartridge change. Skip the Fill Cannula step unless you have also changed your infusion site.

2:27 ^{PM}	
Basal Rate 0.025U/Hr Insulin: 105U	
Status	Menu

Alert	
Your active basal program is empty. 0.000U/Hr	
Confirm	Basal Menu

Setup

Setting/Changing the Time and Date

When you change your battery, the VERIFY screen allows you to edit the time and date.

You can also access the Time/Date SETUP screen by selecting “Setup” from the MAIN MENU.

1. From the Home screen, press **OK** to select “Menu”. Scroll to “Setup” on the MAIN MENU. Press **OK**.

2. Scroll to Time/Date on the SETUP menu. Press **OK**.

3. Press the **OK** button to activate Edit Mode (indicated by flashing cursor).

2:27 ^{PM}	
Basal Rate 0.025U/Hr Insulin: 105U	
Status	Menu

MAIN MENU	
Bolus CGM Suspnd/Resum History Basal Setup Prime/Rewind	
Status	Home

SETUP	
Time/Date	
Sound Advanced	
<<—	Home

4. Use the ▲/▼ buttons to change to your desired settings. Press the **OK** button to confirm your setting and exit Edit mode.

5. Use the ▲/▼ buttons to select the next field. Repeat the above process. Scroll to highlight “Main Menu” and press **OK** button when finished. The MAIN MENU screen will be displayed.

NOTE:

- It is important to have the correct (current) date and time set in your pump. Be sure to confirm the date and time before saving them in your pump.
- If you select the 12-hour time format, the AM/PM indicators will change as you scroll to set the time. Be sure the desired AM or PM selection is correctly displayed when setting the time.
- If you select the 24-hour time format, the time will be shown in military time.

SETUP	
Time/Date	
Hour: Minute	2: 27PM
Mode	12 Hr
Month	Jan
Day	29
Year	2010
◀◀	Home

Daylight Saving Time (certain states and countries only)

“Spring Forward”

If you advance the hour on your pump clock after **11pm but before midnight**, you must also manually forward the date by one day. If you change your pump clock **after midnight**, your pump date will have changed automatically to the appropriate date.

“Fall Back”

It is recommended that you set your clock back **before midnight on Saturday or after 1am on Sunday**. This keeps your pump set to the correct date. Your pump will register an additional hour in the Daily Totals History because the day has essentially been altered to consist of 25 hours. If you change the clock between midnight and 1am, you must also change the date. This will result in a duplicate date entry in your history. (This duplicate entry will contain up to one hour’s worth of insulin delivered.)

Sounds – Setting/Changing

The sound menu only adjusts sounds for pump-related functions. It does not activate the feature. For example, Audio Bolus Sound is adjusted in this menu, but to turn the Audio Bolus feature on, go to the Setup Advanced menu. See *Chapter 9* in *Section I*, pages 43-56. Refer to *Chapter 2* in *Section II*, pages 87-94 to set CGM-related sounds.

Your pump comes pre-loaded with a tune for most Alerts, Reminders and Alarms on medium and high volume settings. This tune plays only for the initial audible notification. If you do not confirm the initial notification, the next sound will be the factory default. If not confirmed, Warnings and Alarms will automatically progress to high volume and vibrate within one hour.

The options from the first SETUP SOUND menu are listed below. Normal Bolus Sound and Temp Basal Sound can be set to one of the following: Vibrate (Vib), Low volume (L), Medium volume (M), High volume (H) or can be shut off (OFF) completely. For safety reasons, some sounds **cannot** be turned off.

Normal Bolus Sound

Audio Bolus Sound (OFF is not an option for this sound setting)

Temp Basal Sound

The options from the second Setup Sound menu are listed below. They can be set to one of the following: Vibrate (Vib), Low volume (L), Medium volume (M), High volume (H) or can be shut off (OFF). For safety reasons, some sounds **cannot** be turned off.

Alert Sound

Reminder Sound (OFF is not an option for this sound setting)

Warning Sound (OFF is not an option for this sound setting)

Alarm Sound (OFF is not an option for this sound setting)

⚠ CAUTION: Unless otherwise recommended by your health care professional, vibrate mode should not be used during sleep. If you are a very sound sleeper, set the alarm volume to high before going to bed.

1. From the MAIN MENU, scroll to “Setup”. Press the **OK** button.
2. Scroll to “Sound”. Press the **OK** button to go to the SETUP SOUND screen.
3. Use the **▲/▼** buttons to scroll to your selection. Press the **OK** button.
4. The cursor will flash to indicate you can edit the selection. Use **▲/▼** buttons to change to desired setting. Press the **OK** button to confirm.

MAIN MENU	SETUP	SETUP SOUND	SETUP SOUND
Bolus	Time/Date	N-Bolus H	Alert L
CGM	Sound	A-Bolus L	Reminder Vib
Suspnd/Resum	Advanced	T-Basal OFF	Warning M
History			Alarm H
Basal			<<— Home —>
Setup			
Prime/Rewind			
Status Home	<<— Home —>	<<— Home —>	

5. Repeat for remaining selections.
6. Scroll to “→” to access second SETUP SOUND menu or scroll to “Home” when finished to return to the Home screen.

The Cartridge

Filling the Cartridge

Refer to the *Instructions for Use* included with your cartridges.

Connecting the Tubing to the Cartridge

To complete this section, you will need the following:

- Filled Animas® 2.0 mL Cartridge (200 unit/2ml)
- Infusion set compatible (standard Luer lock and insulin-compatible tubing) with your Animas® Vibe™ Insulin Pump

⚠ WARNING: The efficacy of your pump cannot be guaranteed if cartridges other than those manufactured by Animas Corporation are used.

Only infusion sets marketed for use with insulin infusion pumps using insulin-compatible tubing and with a standard Luer lock can be used with your Animas® Vibe™ Insulin Pump. The efficacy of your pump cannot be guaranteed if other types of infusion sets are used. If you are unsure about whether your infusion set can be used with your Animas® Vibe™ Insulin Pump, consult your health care team.

Never start the Prime/Rewind sequence on your pump while the infusion set is connected to your body. Failure to disconnect your infusion set from your body before you start the Prime/Rewind process can result in over delivery of insulin, and possible injury or death. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycemia.

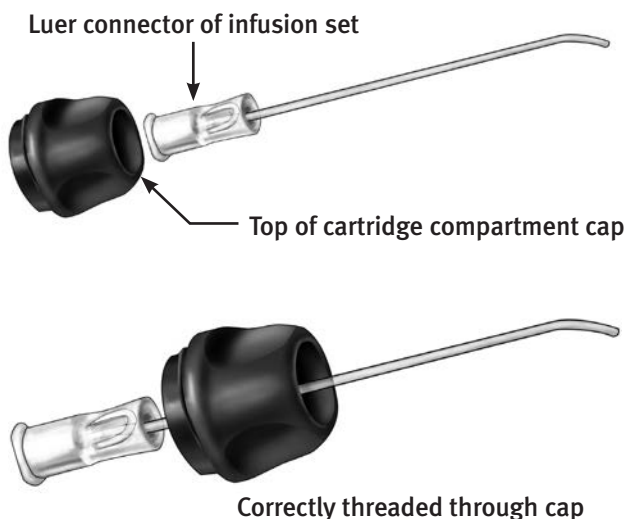
1. Clean the workspace where you will be connecting the infusion set to the cartridge. Wash your hands thoroughly with soap and water.

2. Open sterile infusion set package carefully. If the package is damaged or opened, use another set and contact your supplier.

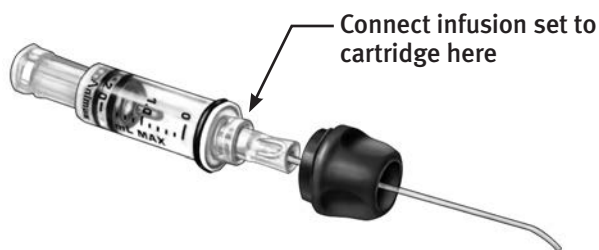
3. Unscrew the cartridge compartment cap from your pump, using a counter-clockwise motion.

4. Remove infusion set tubing cap from the Luer connector. (Not all infusion sets have these caps.)

5. After removing protective cap, thread the Luer connector of the infusion set through the top (smaller) opening of the cartridge compartment cap, being careful not to touch Luer tip with hands or work surface.



6. Remove cap from the filled cartridge tip. To avoid insulin spillage and introduction of air in the cartridge, it should never be filled beyond the 2.0 mL mark. The plunger is properly positioned for maximum fill when the black o-ring nearest to the plunger tip is centered on the 2.0 mL mark. Attach infusion set Luer connector to cartridge tip using clockwise motion until finger tight **and then twist another quarter of a turn.**



⚠ WARNING: Be sure to twist the Luer connector an extra quarter of a turn to ensure a secure connection. If the connection is not secure, insulin may leak around the cartridge, resulting in under delivery of insulin.

7. Put cartridge/tubing assembly aside.

NOTE:

- Check for leaks, cracks or damage each time you change your cartridge and infusion set. To avoid leakage, be sure to tighten the Luer connection securely. You can check for moisture periodically by wrapping a tissue around the Luer connection between the cartridge and infusion set.
- When handling the cartridge, take care not to twist or turn the plunger in the cartridge body. Maintaining straight alignment of the plunger keeps the o-rings properly seated, which minimizes the possibility of introducing air into the cartridge and insulin spillage.

Changing the Cartridge

1. Disconnect infusion set from your body.
2. Unscrew the cartridge cap, leaving tubing connected to the cartridge.
3. With the tubing connected to the cartridge, pull cartridge straight out of your pump.
4. Disconnect tubing from cartridge and discard. Proceed with filling the new cartridge as outlined above.

Priming your Pump and Infusion Set

NOTE: As each step is completed, the check box on the ezPrime menu will be shaded.

⚠ WARNING: Never prime tubing or tighten the cartridge cap while the infusion set is connected to your body. Failure to disconnect your infusion set from your body before performing this step can result in over delivery of insulin, and possible injury or death. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycemia.

1. Make sure you are disconnected from your pump.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

2. From the MAIN MENU, select “Prime/Rewind”.

ezPrime	REWIND MOTOR
☒ Rewind ☐ Load Cart ☐ Prime ☐ Fill Cannula	Disconnect infusion set from your body!
Main Menu	Go Rewind Cancel

3. On the ezPrime menu, “Rewind” is highlighted. Press **OK**. The REWIND MOTOR screen is displayed.

4. Scroll up to “Go Rewind”. Press **OK**. Your pump will rewind the piston rod.

NOTE: Before starting the rewind, your pump will vibrate as it performs a self test.

REWIND MOTOR	REWIND ACTIVE
Disconnect infusion set from your body!	Please wait. Full rewind required.
Go Rewind Cancel	<<-----<<-----<<-----<<

5. When the rewind action is complete, the REWIND COMPLETE screen is displayed. Your pump will beep once to let you know the rewind is complete.

REWIND ACTIVE
Position: 160U
<<-----<<-----<<-----<<
Stop

NOTE: If using a partially filled cartridge, you can select Stop during the Rewind Active function to stop the rewind at the position desired. After every third rewind, your pump is required to do a Full Rewind and will not offer the option of selecting the “Stop” position. A Full Rewind is always required when a battery is inserted.

6. Insert your filled cartridge.

7. Secure cartridge compartment cap to pump by turning in a clockwise motion until finger tight but **Do Not** over tighten.

⚠ WARNING: Never tighten the cartridge cap while the infusion set is connected to your body. Failure to disconnect your infusion set from your body before performing this step can result in over delivery of insulin, and possible injury or death. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycæmia.

ezPrime
☒ Rewind ☐ Load Cart ☐ Prime ☐ Fill Cannula
Main Menu

NOTE: • If screen display has timed out while loading your cartridge, select Prime/Rewind from the MAIN MENU and highlight “Load Cart” from the ezPrime menu. Press **OK** to display the REWIND COMPLETE screen. Continue with Step 8.

- You can only highlight “Load Cart” from the ezPrime menu after the rewind action is complete. This is true for all ezPrime menu options: you can only proceed to the next action once the previous action is complete.

8. On the REWIND COMPLETE screen, “Continue” is highlighted. Press **OK**. Your pump will align the piston rod with the cartridge. The LOAD CARTRIDGE ACTIVE screen is displayed, followed by the PRIME screen. Your pump will beep once to let you know the cartridge is aligned with the piston rod.

REWIND COMPLETE
Disconnect set. Load U100 cartridge. Attach cap.
Continue Cancel

LOAD CARTRIDGE ACTIVE
Please wait.
>>----->>----->>----->>

PRIME
Be sure set is disconnected from your body.
Insulin: 200U
Continue Cancel

9. On the PRIME screen, “Continue” is highlighted. Press **OK**.

DELIVER PRIME
Press AND HOLD OK button while priming tubing.
Insulin: 200U
Go Prime Cancel

10. The DELIVER PRIME screen is displayed. **Be sure the infusion set is not connected to your body until the prime is complete.**

⚠ WARNING: Never prime while the infusion set is connected to your body. Failure to disconnect your infusion set from your body before performing this step can result in over delivery of insulin, and possible injury or death. If your pump sustains internal damage, the amount of unintended insulin delivery could be significant. This could result in serious injury or death from hypoglycæmia.

CHAPTER 3 - GETTING YOUR PUMP READY

11. Make sure “Go Prime” is highlighted. **Press and hold** the **OK** button until you see 5 drops of insulin come out the end of your infusion set. This means your tubing is primed. The PRIMING ACTIVE screen is displayed, followed by the PRIMING DONE screen.

PRIMING ACTIVE	PRIMING DONE
Press AND HOLD OK button while priming tubing.	18U Primed 182U Remaining
Insulin: 182U	
>>----->>----->>-----	

NOTE: The maximum Prime amount is 20U at a time. The amount of Prime insulin displayed on the PRIMING DONE screen may differ from the amount displayed during the Priming procedure by $\pm 2U$. If additional priming is required, select “Prime” a second time from the ezPrime screen and repeat the steps for priming until you are sure 5 drops of insulin come out the end of your infusion set.

Refer to the *Instructions for Use* included with your infusion set for proper insertion guidelines. See *Selecting the Infusion Site and Inserting the Infusion Set*, page 19 in this chapter.

12. From the ezPrime menu, “Fill Cannula” is highlighted. Press the **OK** button. The FILL CANNULA screen is displayed.

NOTE: This step is not necessary for needle sets.

ezPrime	FILL CANNULA
■ Rewind ■ Load Cart ■ Prime ☐ Fill Cannula	Amount 0.00 U
Go	Go
Main Menu	Main Menu

13. Use the **▲**/**▼** buttons to enter the amount of insulin needed to fill the cannula. Refer to the *Instructions for Use* included with your infusion set for details on how much insulin is required to fill the cannula. Press **OK**. “Go” is highlighted. Press **OK** to fill the cannula.

NOTE: The maximum Fill Cannula amount is 1U at a time.

If your pump is suspended, the screen will alert you with the ezPrime “Pump suspended” screen. You must resume delivery of your pump in order to complete the Priming function.

ezPrime
Pump suspended. Priming is disabled.
Rewind Home

NOTE: The Fill Cannula step is not required for your pump to operate. For example, when you prime your pump after a battery change and you are not inserting a new infusion set, this step is not necessary. Filling the cannula when not necessary can result in unwanted delivery of insulin.

Selecting the Infusion Site and Inserting the Infusion Set

Your health care team will review appropriate site selections and techniques for insertion based on your body type. Refer to the *Instructions For Use* included with your infusion set for proper insertion guidelines.

⚠ WARNING:

- **Do Not attempt to insert the infusion set into your body until you have been trained by your health care team. Improper insertion of your infusion set can lead to death or serious injury.**
- **Choose an area at least 7.6 centimeters (3 inches) away from your CGM Sensor where you plan to inject insulin, to insert the infusion set. Avoid skin sites with tattoos, or areas with rough patches or scarring from your pump or insulin injections.**

Changing the Cartridge and Infusion Set

Cartridges and infusion sets require replacement and are not to be reused. Infusion sets should be replaced approximately every 2-3 days or as directed by your health care team. Refer to the insulin labeling and follow the direction of your health care team for frequency of replacing the cartridge.

⚠ CAUTION: Occasionally check the infusion set tubing for any damage, air bubbles, leaks or kinking, which may restrict or stop insulin delivery and result in under infusion.

⚠ WARNING:

Cartridges are for single use only. Re-use of a cartridge can adversely affect product performance, and can contribute to infection, insulin contamination, and under-delivery of insulin.

CHAPTER 4 - USING THE NORMAL BOLUS FEATURE

This chapter covers the basics of a Normal bolus, which is used to cover your insulin needs.

Your pump also offers advanced bolus features. See *Chapter 9* in *Section I*, pages 43-56.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU, select “Bolus”.

2. The cursor will flash over the amount field to indicate that it can be edited. Use the ▲/▼ buttons to enter desired bolus amount. Press **OK**.

NORMAL BOLUS	
Amount	0.00 u
Go	
Main Menu	

NORMAL BOLUS	
Amount	2.35 u
Go	
Main Menu	

NORMAL BOLUS	
Amount	2.35 u
Go	
Main Menu	

3. Go is highlighted. Press **OK** to deliver the bolus.

4. The DELIVERING bolus screen is displayed. If you have activated the Normal Bolus sound in the SETUP SOUND menu, your pump will beep to confirm start of delivery, as well as when delivery is complete.

DELIVERING	
	2.00 u
Press any function button to cancel.	

NOTE: During a bolus delivery, you can stop delivery at any time by pressing any button on the front panel of your pump. The Warning screen shown here will be displayed. Confirm the Warning by pressing **OK** and check your Bolus History for the amount delivered.

Warning	
Bolus delivery canceled by user button press.	
Delivered: 1.35U of 2.35U	
Confirm	

NOTE: You can check when you last gave a bolus by looking in History or Status. These features are covered later. See *Chapter 7*, pages 33-38, and *Chapter 8*, pages 39-42, in *Section I*.

NOTE: If you have Advanced Bolus and Reminders features turned on, the BOLUS MENU shown on the right will be displayed when you select “Bolus” from the MAIN MENU. Select “Normal” and press **OK**. Follow steps 2 through 4 in this chapter.

BOLUS MENU	
Normal	
ezCarb	
ezBG	
Combo Bolus	
Reminders	
Main Menu	

CHAPTER 5 - USING BASAL PROGRAM FEATURES

You can program your pump to display either 1 or 4 basal program options. Basal insulin is delivered continuously to help keep your BG in target between meals. Having more than one pre-set basal program makes it easy for you to switch based on your needs including weekends, weekdays, shift work, and menstruation. If you are new to pumping, your health care team may suggest you first become comfortable with one program before using multiple basal programs. The factory default displays one basal program and the temporary basal program. To display multiple basal options, see *Chapter 9 in Section I*, pages 43-56.

⚠ CAUTION: The lowest basal delivery amount possible is 0.025U/Hr. The highest basal delivery amount possible is 25U/Hr or the Max Basal amount you set in the Setup Advanced menu in *Chapter 11 in Section I*. This applies to any basal rate programmed in any basal program, and to any adjusted basal rate you set with the Temporary Basal Feature (see page 27).

Setting a Basal Program

Each basal program can be set with up to 12 different basal rates (doses) in a 24-hour period. These 12 start times can be set to accommodate your changing basal needs throughout the day. For example, your body may need more insulin in the early morning to compensate for the “dawn phenomenon.” You can program time segments to begin at any hour or half hour.

NOTE: The / buttons will move the cursor through fields when not in Edit mode. When in Edit mode, the / buttons will change the value of the field. If the cursor is flashing, that means you can edit the entry. Use the  button to start/stop Edit mode.

Use the *My Information* chart in *Chapter 6 in Section III*, pages 161-164 to record and enter your basal program times and doses as recommended by your health care team.

1. From the MAIN MENU, select “Basal”. Press .

MAIN MENU	
Bolus	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	
Status	Home

The BASAL MENU displays the following:

- Total basal insulin programmed for the 24-hour period
- Temp (if you wish to program a Temporary Basal rate)
- The active basal program, designated by number and by name, as well as an “A” to indicate the active program. (If you have activated multiple basal programs in the Setup Advanced menu, all 4 basal program options will be displayed as shown on the far right.)

BASAL MENU	
Total	0.00U
Temp	
A1-WEEKDAY	
Main Menu	

BASAL MENU	
Total	0.00U
Temp	
A1-WEEKDAY	
2-other	
3-weekend	
4-exercise	
Main Menu	

CHAPTER 5 - USING BASAL PROGRAM FEATURES

2. Scroll to select the program “1-WEEKDAY” and press **OK**.

NOTE: You do not have to Suspend your pump to edit an active program. When you select “Edit” from the BASAL MENU, your pump automatically suspends delivery. When you exit the Edit mode, the active program delivery automatically resumes.

BASAL MENU	
Total	0.00U
Temp	
A1-WEEKDAY	
Main Menu	

3. The BASAL OPTIONS screen is displayed. “Edit” is highlighted. Press the **OK** button. From the EDIT BASAL screen, you can edit the basal segments of the selected program.

BASAL OPTIONS	
A1-WEEKDAY	
Total	0.00U
Clear	
Edit	
Review	
Go	
Main Menu	

EDIT BASAL		
Total		0.00U
Start	E	U/Hr
12:00A		0.000
--:--		--.---
Save/Review		

4. Scroll to the desired “U/Hr” field. Press **OK** to activate Edit mode (indicated by flashing cursor).

EDIT BASAL		
Total		0.60U
Start	E	U/Hr
12:00A		0.025
--:--		--.---
Save/Review		

5. Use **▲/▼** buttons to set desired basal rate. Press **OK** to confirm and exit Edit mode for this field.

EDIT BASAL		
Total		0.60U
Start	E	U/Hr
12:00A		0.025
4:00A		--.---
Save/Review		

6. Scroll down to select the next “Start” time field. Press the **OK** button to activate Edit mode (indicated by flashing cursor).

NOTE: The next available empty basal segment will appear automatically as you program the previous segment. If the next empty basal segment does not appear, you have programmed all 12 possible segments.

EDIT BASAL		
Total		13.60U
Start	E	U/Hr
12:00A		0.025
4:00A		0.675
--:--		--.---
Save/Review		

7. Change next “Start” time field as desired, press the **OK** button to exit Edit mode. Segments can start on the hour or half hour. The end time of the current time segment is always assumed to be midnight.

NOTE: The 24-hour Total changes automatically as you change U/Hr settings.

8. Continue until basal segments have been set as recommended by your health care team.
9. When finished, scroll to “Save/Review” and press **OK**. *If you have edited the active program, it is now resumed automatically.* The BASAL OPTIONS screen is displayed.

Warning	
Basal edit not saved. Basal delivery suspended.	
Edit Basal	

NOTE: If your screen display has timed out (gone to sleep) or if an Alarm/Warning appears before you have selected Save/Review while editing, a Warning screen will remind you the basal edit has not been saved. See *Chapter 11 in Section I*, pages 73-84.

10. “Review” is highlighted. Press **OK** to review your entries for accuracy. Your basal segment settings are shown (5 on first screen, 5 on second screen and 2 on last screen). If you have more than 5 segments programmed, scroll to “Next” to see second and third screens as desired.

BASAL OPTIONS	
A1-WEEKDAY	
Total	13.60U
Clear	
Edit	
Review	
Go	
Main Menu	

11. “Options” is highlighted. Press **OK**. The BASAL OPTIONS screen is displayed.

a. If you have edited and saved/reviewed the active program, it is resumed automatically. You can also select “Go” and the Home screen is displayed, which shows the current rate of delivery for the program that is active.

b. If you have edited an inactive program and wish to activate it, select “Go” from the BASAL OPTIONS screen. When you select “Go”, the Home screen is displayed, which shows the current rate of delivery for the program that is active.

BASAL OPTIONS	
A1-WEEKDAY	
Total	13.60U
Clear	
Edit	
Review	
Go	
Main Menu	

Adding/Changing Segments in an Existing Basal Program

- From the BASAL MENU, select desired program.
- “Edit” is highlighted. Press **OK**.
- Scroll to highlight the field you wish to change or to next available blank line to add a segment. Press **OK** to activate Edit mode. (The cursor will flash to indicate Edit mode.)
- Use **▲/▼** buttons to set Start times and U/Hr amounts.
- Check that the AM/PM settings are correct.

NOTE:

- If you program a segment to start at the same time as an existing segment, the previously entered segment is deleted.
- If you program a segment to start at a time that precedes an existing segment, the new segment is automatically inserted in the correct place. You must then scroll to the new segment, highlight the corresponding U/Hr field and enter or change amount, if desired.

6. When finished, scroll to “Save/Review” and press **OK**. If you have edited the active program, it is now resumed automatically. The BASAL OPTIONS screen is displayed.

a. Select “Review” from the BASAL OPTIONS screen to review your entries for accuracy. Your basal segment settings are shown (5 on first screen, 5 on second screen and 2 on last screen). If you have more than 5 segments programmed, scroll to “Next” to see second and third screens as desired.

b. If you have edited an inactive program, select the program from the BASAL MENU. Press **OK**. Select “Go” from the BASAL OPTIONS screen to activate the program you have selected.

When you select “Go”, the Home screen is displayed, which shows the current rate of delivery for the program that is active. (Or you can simply wait for your pump display to time out. When you press any button, your active basal program rate information is displayed on the Home screen.)

⚠ CAUTION: Always review changes to your basal program to be sure they are correct. Incorrect basal rates can result in under or over delivery of insulin. See *Reviewing Basal Programs* below.

Reviewing Basal Programs

1. From the BASAL MENU, scroll to highlight desired program. Press **OK**.

2. Scroll to “Review” from the BASAL OPTIONS screen. Press **OK**. Your basal segment settings are shown (5 on first screen, 5 on second screen and 2 on last screen). If you have more than 5 segments programmed, scroll to “Next” to see second and third screens as desired.

BASAL OPTIONS	
A1-WEEKDAY	
Total	13.60U
Clear	
Edit	
Review	
Go	
Main Menu	

A1-WEEKDAY	
Total	13.60U
Start	U/Hr
12:00A	0.025
4:00A	0.675
--:--	--:--
Options	Next

3. When finished, “Options” is highlighted. Press **OK**.

4. Scroll to “Main Menu” and press **OK**. The MAIN MENU screen is displayed. *The active basal program continues.*

5. If reviewing an inactive program and you wish to activate it, select the program you wish to activate from the BASAL MENU screen. Press **OK**.

6. Select “Go” from the BASAL OPTIONS screen to activate the program. The Home screen is displayed to show the current rate per hour of the program you have activated.

Clearing Basal Programs

This feature allows you to clear all information from a basal program.

1. From the BASAL MENU, scroll to desired program.
2. From the BASAL OPTIONS screen, scroll to “Clear”. Press **OK**.

If you press **OK** to select “Clear”, your pump will check to be sure you want to clear all the segments of the basal program selected. The Alert screen shown here is displayed. If you do wish to clear all the basal segments of the selected program, scroll to “Clear Program” and press **OK**.

If you do not wish to clear all the basal segments, scroll to “Basal Options” and press **OK**. The BASAL OPTIONS screen will be displayed.

BASAL OPTIONS	
A1-WEEKDAY	
Total	13.60U
Clear	
Edit	
Review	
Go	
Main Menu	

Alert	
Clear Program deletes all basal segments in this program.	
Clear Program	
Basal Options	

If all segments of your active basal program are set to 0.000 U/Hr your pump will not deliver any basal insulin. Each time you wake up your pump, the Alert screen shown here is displayed. If you have turned on the sound for Alerts, you will also be notified by a beep or vibrate. This Alert screen does not progress to higher audible alarms. You have the option to either select “Confirm” to quickly go to the MAIN MENU screen or select “Basal Menu” to reset rates in your active program. For more information see *Chapter 11* in *Section I*, pages 73-84.

Alert	
Your active basal program is empty. 0.000U/Hr	
Confirm	
Basal Menu	

Temporary Basal Feature

This feature allows you to increase your active basal delivery rate for events such as sick days or decrease for events such as exercise. You can decrease your basal rate by up to 90% (in 10% decrements) or increase your basal rate by up to 200% (in 10% increments). You can also set to OFF. You can set the duration up to 24 hours in half-hour increments. (If you have activated multiple basal programs in the Setup Advanced menu, all 4 basal program options will be displayed as shown on screen example below, right.)

1. From the BASAL MENU, scroll to “Temp”. Press **OK**.

BASAL MENU	
Total	0.00U
Temp	
A1-WEEKDAY	
Main Menu	

BASAL MENU	
Total	0.00U
Temp	
A1-WEEKDAY	
2-other	
3-weekend	
4-exercise	
Main Menu	

CHAPTER 5 - USING BASAL PROGRAM FEATURES

2. The “Change” % field will flash to indicate Edit mode. Use the / buttons to enter the percentage change desired. Press the button to exit Edit mode.

A1-WEEKDAY TEMP BASAL
Change: -40%
Duration: 2.0Hr
Go
Main Menu

A1-WEEKDAY TEMP BASAL
Change: 0%
Duration: 4.0Hr
Go
Main Menu

A1-WEEKDAY TEMP BASAL
Change: -40%
Duration: 4.0Hr
Go
Main Menu

3. The “Duration” field is highlighted. Press to activate Edit mode.

4. Use the / buttons to enter the duration desired. Press to exit Edit mode.

⚠ CAUTION: The lowest basal delivery amount possible is 0.025U/Hr. When you set a negative temporary basal rate, your pump will beep and display an Alert screen to remind you of the minimum delivery limit. This screen will display once for 4 seconds and give one audible alert (if you turned on Alert sounds in Setup). Your pump will not deliver any temporary basal set below 0.025 U/Hr. Any temporary basal rate set below 0.025 U/Hr will automatically be re-set to 0.025 U/Hr.

If you would like to deliver a temp basal amount less than 0.025 U/Hr, you can select “OFF” in the “Change” % field in the screen above. This will set the temp basal rate to 0.0 U/Hr for the duration selected.

Alert
Temp Active Minimum Basal rate limited to 0.025U/Hr

5. “Go” is highlighted. Press to activate Temp Basal.

6. The Home screen is displayed and shows your Temp Basal is active, the percentage change, the duration and how much time is left. When the duration of time is complete, your pump will automatically resume the active basal program.

NOTE: If you turned on the Temp Basal sound in Setup, your pump will beep once every 30 minutes to remind you of Temp Basal status.

2:27 ^{PM}
TEMP BASAL -40% 4.0 Hr Time Left 3.2 Hr Insulin: 105U
Status Menu

Canceling a Temporary Basal Program

1. From the BASAL MENU, select “TEMP BASAL”. Press **OK**.
2. Details of the current active Temp Basal program will be displayed. Scroll up to “CANCEL” and press **OK**.

Your previously active basal program will be activated and the Home screen will be displayed to show the current rate per hour of the active basal program.

A1-WEEKDAY TEMP ACTIVE
0.675 U/Hr -40% = 0.405 U/Hr Time left 1.2 Hr
CANCEL
Main Menu

NOTE: If you Suspend your pump while a Temp Basal program is active, the Temp Basal program will be canceled and an Alert screen will notify you that the Temp Basal program has been canceled. This Alert is displayed once and gives an audible tone once (if you turned on Alert sounds in Setup). Temp Basal is also canceled when you change the battery and/or prime.

Alert
Pump Suspended
If active, Temp Basal & Combo Bolus have been canceled.

⚠ CAUTION: When you switch to another basal program or set a Temp Basal, you will most likely be changing the total insulin units delivered over a period of time. Be sure to review the total insulin units before you switch basal programs or set a Temp Basal. Units that are too high or too low may result in a hypoglycemic or hyperglycemic event.

CHAPTER 6 - SUSPEND/RESUME FEATURE

This feature allows you to stop and restart delivery quickly and easily.

It also cancels delivery of any Temp Basal or Bolus, including Combo Bolus that may be currently active. The Combo Bolus feature is covered in *Chapter 9* in *Section I*, pages 43-56.

Suspending Delivery

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU, scroll to “Suspnd/Resum” and press **OK**.

Pump Delivery	
Suspend	
Main Menu	

2. “Suspend” is highlighted. Press **OK**.

The screen will display a message reminding you that this mode not only suspends your active basal delivery but also *cancels* any Temp Basal or Combo Bolus that may be active.

Alert
Pump Suspended
If active, Temp Basal & Combo Bolus have been canceled.

2:27 PM	
	
SUSPENDED	
Basal Rate	
0.675U/Hr	
Insulin: 105U	
Status	Menu

3. The Home screen is then displayed, showing that pump deliveries are suspended.

⚠ CAUTION:

- While insulin delivery is suspended, your CGM session will remain active, but CGM readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM readings will start recording and displaying again.
- If you want to temporarily suspend insulin delivery but still view CGM readings, do not use the suspend delivery feature. Instead, you can program a temporary basal of 0 units for the time period you want basal delivery suspended, and still be able to view CGM readings.

NOTE:

- If you suspend insulin delivery during the 2-hour CGM Calibration Startup period, the calibration sequence will continue and the CGM session will remain active even though insulin delivery is suspended.
- See *Section II*, pages 85-140 for information on CGM functions.
- Periodically, your pump will beep (or vibrate if that is the setting you selected) to remind you of the Suspend status. If not confirmed, the beeps will progress to high volume in one hour. You can confirm the Warning to reset the audible sequence. See *Chapter 11* in *Section I*, pages 73-84.

Warning**No delivery.****Pump is
suspended.****Confirm****Resuming Delivery**

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU, scroll down to “Suspnd/Resum” and press **OK**.

Pump Suspended at 2:27PM 2 Oct, 2010	
Resume	
Main Menu	

2. “Resume” is highlighted. Press **OK**.

3. The Home screen is displayed to show you that your pump is no longer in Suspend mode. Your previously active basal program is automatically resumed.

2:27 ^{PM}	
	
Basal Rate 0.025U/Hr Insulin: 105U	
Status	Menu

CHAPTER 7 - HISTORY FEATURE

Your pump stores important records for your review. You can access your pump's history and view it directly on your pump screen or you can use the Diasend® Web-based Diabetes Management System to track, review and analyze pump history on your computer. Visit www.diasend.com/animas for more information. To view CGM History, see *Chapter 7* in *Section II*, pages 119-122.

Your pump stores basal rates, boluses, alarms and settings. Your pump stores these records indefinitely, even when batteries are removed.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

From the MAIN MENU, select "History". The HISTORY menu is displayed.

Bolus History

Your pump displays the last 500 Bolus records.

1. From the HISTORY menu, select "Bolus".

The screen displays the following:

- Bolus Record number
- Date of bolus
- Time of bolus
- Type of bolus delivered
 - Normal
 - Combo
 - Audio
- Amount of bolus programmed and delivered
- Status of bolus
 - ACTIVE
 - COMPLETED
 - CANCELED
- If ezBG or ezCarb was used

HISTORY	
Bolus	
Total Daily Dose (TDD)	
Alarm	
Prime	
Suspend	
Basal	
Main Menu	

BOLUS	
Record	1
23 Mar, 2010	
1:13PM	
NORMAL	
2.80U of 2.80U	
COMPLETED	
ezCarb	
<==	

2. To view other Bolus records first scroll up to highlight the record field. Press **OK** to activate Review mode (indicated by flashing cursor).

- Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.
- When finished reviewing, press **OK** to exit Review Mode.
- “<==” is highlighted. Press **OK** to return to the HISTORY menu.

Total Daily Dose (TDD) History

Your pump displays the last 120 TDD records.

- From the HISTORY menu, select “Total Daily Dose (TDD)”.

This screen displays the following:

- Record number
- Date of record
- If Temp Basal was active on that date
- If Suspend was activated on that date
- Total Bolus for the date
- Total Basal for the date
- Total dose for the date

HISTORY
Bolus
Total Daily Dose (TDD)
Alarm
Prime
Suspend
Basal
Main Menu

TDD
Record 1
23 Mar, 2010
Temp No
Suspend No
Bolus 6.200U
Basal 0.700U
TOTAL = 6.900U
<==

NOTE: Each daily total is the total delivered since midnight.

- Scroll up to highlight the record field. Press **OK** to activate Review Mode (indicated by flashing cursor).
- Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.
- When finished reviewing, press **OK** to exit Review Mode.
- “<==” is highlighted. Press **OK** to return to the HISTORY menu.

Alarm History

Your pump History menu displays the last 30 alarm records related to insulin delivery. Alarms related to CGM functions can be displayed under the CGM Menu options (see *Chapter 7 in Section II*, pages 119-122).

1. From the HISTORY menu, select “Alarm”.

The screen displays the following:

- Record number
- Date of alarm
- Time of alarm
- Alarm Code
- Alarm Type

HISTORY	ALARM
Bolus	Record 1
Total Daily Dose (TDD)	23 Mar, 2010
Alarm	01:13PM
Prime	Code
Suspend	X-XXXXXXXX
Basal	EMPTY
Main Menu	CARTRIDGE
	<==

2. Scroll up to highlight the record field. Press **OK** to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the **▲/▼** buttons to scroll to other records.

4. When finished reviewing, press **OK** to exit Review Mode.

5. “<==” is highlighted. Press **OK** to return to the HISTORY menu.

Prime History

Your pump displays the last 60 Prime and Fill Cannula records. Prime and Fill Cannula records are stored as separate records.

1. From the HISTORY menu, select “Prime”.

The screen displays the following:

- Record number
- Date of prime
- Time of prime
- Amount of prime

HISTORY	PRIME
Bolus	Record 1
Total Daily Dose (TDD)	23 Mar, 2010
Alarm	01:13PM
Prime	Primed
Suspend	Total 18.0U
Basal	
Main Menu	<==

2. Scroll up to highlight the record field. Press **OK** to activate Review Mode (indicated by flashing cursor).

CHAPTER 7 - HISTORY FEATURE

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

The screen displays the following:

- Record number
- Date of cannula fill
- Time of cannula fill
- Amount of cannula fill

PRIME	
Record	2
23 Mar, 2010 01:15PM	
Fill Cannula	
Total	1.0U
<==	

4. When finished reviewing, press **OK** to exit Review Mode.

5. “<==” is highlighted. Press **OK** to return to the HISTORY menu.

Suspend History

Your pump displays the last 30 Suspend records.

1. From the HISTORY menu, select “Suspend”.

The screen displays the following:

- Record number
- Date and time pump delivery was suspended
- Date and time pump delivery was resumed

HISTORY
Bolus
Total Daily
Dose (TDD)
Alarm
Prime
Suspend
Basal
Main Menu

SUSPEND
Record
1
Suspended
23 Mar, 2010 01:13PM
Resumed
23 Mar, 2010 01:13PM
<==

2. Scroll up to highlight the record field. Press **OK** to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the ▲/▼ buttons to scroll to other records.

4. When finished reviewing, press **OK** to exit Review Mode.

5. “<==” is highlighted. Press **OK** to return to the HISTORY menu.

Basal History

Your pump keeps track of whenever there has been a change in a basal rate and will display the last 270 basal “rate change” records.

1. From the HISTORY menu, select “Basal”.

The screen displays the following:

- Record number
- Date and time basal rate was adjusted
- Basal rate adjustment

HISTORY	BASAL
Bolus	Record 1
Total Daily	23 Mar, 2010
Dose (TDD)	01:13PM
Alarm	Rate = 0.670
Prime	
Suspend	
Basal	
Main Menu	<==

2. Scroll up to highlight the record field. Press **OK** to activate Review Mode (indicated by flashing cursor).

3. Record 1 indicates the most recent record. Use the **▲/▼** buttons to scroll to other records.

4. When finished reviewing, press **OK** to exit Review Mode.

5. “<==” is highlighted. Press **OK** to return to the HISTORY menu.

NOTE: Basal History records each basal rate change. When no basal is being delivered, the Basal History Record will show 0 units delivered. This can happen for the following reasons:

- Cartridge change
- Battery change
- Suspend
- Alarm
- Basal segment set to 0
- Basal edit screen accessed
- Prime menu accessed
- Loss of prime

CHAPTER 8 - STATUS FEATURE

This feature gives you easy access to a summary of information about your pump's current programming and performance. There are seven Status screens.

1. From the MAIN MENU or from the Home screen, scroll to "Status" and press **OK**.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

2:27PM	
Basal Rate	
0.025U/Hr	
Insulin: 105U	
Status	Menu

Status Screen 1 – Active Basal

The screen displays the following information:

- Which basal program is currently active
- The 24-hour total for the active basal program
- Units per hour currently being delivered
- Insulin currently remaining in cartridge

STATUS 1 ACTIVE BASAL
A1-WEEKDAY
24-Hr Total
13.60U
0.675U/Hr
Insulin: 105U
Home ← →

To move to the next STATUS screen, press **OK** with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press **OK**.

Status Screen 2 – IOB, Last Bolus

The screen displays the following information:

- Amount of insulin currently "on board" (IOB). For more information on this feature, see *Chapter 9 in Section I*, pages 43-56.
- Type and amount of last completed bolus
 - N = Normal
 - C = Combo (normal portion only)
 - A = Audio
- Time and date of last bolus

STATUS 2 IOB=1.70U LAST BOLUS
N 3.30U
9:55AM
8 Jul, 2010
Home ← →

To move to the next STATUS screen, press **OK** with "→" highlighted at the bottom of the screen.

To return to the Home screen, highlight "Home" and press **OK**.

Status Screen 3 – Delivery Today

The screen displays the following information since midnight and up to the current time stored in the pump:

- Insulin type
- If Temp Basal has been active
- If Suspend has been active
- Total bolus amount delivered
- Total basal amount delivered
- Total insulin delivered (*excluding* prime amounts)

To move to the next STATUS screen, press **OK** with “→” highlighted at the bottom of the screen.

To return to the Home screen, highlight “Home” and press **OK**.

STATUS 3 DELIVERY TODAY	
U100	
Temp	No
Suspend	No
Bolus	9.400U
Basal	0.200U
TOTAL =	9.600U
Home	← →

Status Screen 4 – Combo Bolus

The screen displays the following information:

- Most recent Combo Bolus status
 - Active or Completed or Canceled
 - Start date
 - Start time
 - End time
 - Amount delivered (if active, shows amount delivered as of current time stored in the pump)

For more information on Combo Bolus, see *Chapter 9* in *Section I*, pages 43-56.

To move to the next STATUS screen, press **OK** with “→” highlighted at the bottom of the screen.

To return to the Home screen, highlight “Home” and press **OK**.

STATUS 4 COMBO BOLUS CANCELED	
23 Mar, 2010	
Start	07:23AM
End	07:31AM
Delivered:	
3.28/9.00U	
Home	← →

Status Screen 5 – Temp Basal

The screen displays the following information:

- Most recent Temp Basal status
 - Active/Inactive
 - Start date
 - Start time
 - End time
 - % adjustment

To move to the next STATUS screen, press **OK** with “→” highlighted at the bottom of the screen.

To return to the Home screen, highlight “Home” and press **OK**.

STATUS 5 TEMP BASAL ACTIVE	
23 Mar, 2010	
Start	04:00PM
End	06:00PM
Change:	-50%
Home	← →

Status Screen 6 – Pump Information

The screen displays the following information:

- Pump serial number
- CGM Transmitter ID/Serial Number (see *Chapter 2 in Section II*, pages 87-94)
- Software versions

STATUS 6 PUMP INFO	
S/N	XXXXXX-XX
Tx S/N	XXXXXX
Revs	
M=XXX.XX.X	P=XXX
D=XXX	L=X.X
W=XXX	
G=XX.XX.XX.XX	
Home	← →

To move to the next STATUS screen, press **OK** with “→” highlighted at the bottom of the screen.

To return to the Home screen, highlight “Home” and press **OK**.

Status Screen 7 – Additional Pump Codes

The screen contains information that will be useful to Customer Support or your local Animas distributor (see page 187) if requested.

STATUS 7 CODES	
_XX_XX_XX_XX	
X XX XX XX XX	
Y XX XX XX XX	
Z XX XX XX XX	
Home	← →

To move to the next STATUS screen, press **OK** with “→” highlighted at the bottom of the screen.

To return to the Home screen, highlight “Home” and press **OK**.

CHAPTER 9 - ADVANCED FEATURES / SETUP AND ACTIVATION

Now you have made it through the basics! Your pump offers many advanced features that you may find helpful in managing your diabetes. Consult with your health care team to determine which advanced features and settings are appropriate for you.

⚠ WARNING: Be sure to discuss which advanced features and settings are right for you with your health care team. Many of the advanced features/settings require input from your health care team before you begin using the feature. Use of incorrect settings on certain advanced features can result in over delivery or under delivery of insulin.

This chapter tells you how to set up and turn on the advanced features. *Chapter 10 in Section I*, pages 57-72, covers how to use each advanced feature.

From the MAIN MENU screen, select “Setup”.
Then select “Advanced” from the SETUP screen and press **OK**.

MAIN MENU	SETUP
Bolus	Time/Date
CGM	Sound
Suspend/Resume	Advanced
History	
Basal	
Setup	
Prime/Rewind	
Status Home	⏪ Home

The SETUP ADV 1 screens allow you to program personal settings that will be used with the ezCarb and ezBG features.

Setup Advanced Screen 1 – Personal Settings - Insulin to Carb (I:C) Ratios

An Insulin to Carb (I:C) ratio is the amount of carbs you can cover with one unit of insulin. Your health care team may recommend you use different Insulin to Carb (I:C) ratios for different times of the day. When you use the ezCarb feature, your pump will automatically select the I:C ratio for the current time stored in the pump.

This screen allows you to set different I:C ratios for 12 different time slots.

NOTE: If you set only one Insulin to Carb Ratio, it will be used for the entire 24-hour period.

1. From the SETUP ADV 1 screen, scroll up to “I:C Ratio”. Press **OK**.
2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the **▲/▼** buttons to scroll to the “1U:” (grams) field.
3. Press **OK** to change to flashing cursor for Edit Mode.
4. Use the **▲/▼** buttons to change to desired setting.
5. Press **OK** when setting is made.

SETUP ADV 1
I:C Ratio
ISF
BG Target
Home ⏪ ⏩

I:C Ratio 1 of 12
Time: 12:00A
1U: 13g
⏪ ⏩
Done Home

6. To move to the next I:C Ratio screen, scroll to “-->” and press **OK**.

7. Scroll up to the “Time” field and press **OK** to change to flashing cursor for Edit Mode.

8. Use the **▲/▼** buttons to change the segment start time. Press **OK**.

9. Scroll to the “1U:” (grams) field and press **OK** to change to flashing cursor for Edit mode.

10. Use the **▲/▼** buttons to change the “1U:” (grams) field as desired. Press **OK**. Repeat to set remaining segments per your health care team’s recommendations.

To review your settings, highlight “-->” and press **OK** to scroll through each segment. Confirm the times and setting values are correct.

When finished, scroll to “Done” and press **OK** to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to “Home” and press **OK**. For more information, see *Chapter 10* in *Section I*, pages 57-72.

I:C Ratio 2 of 12	
Time:	6:00A
1U:	15g
<<--	-->>
Done	Home

Setup Advanced Screen 1 – Personal Settings - Insulin Sensitivity Factor (ISF)

An Insulin Sensitivity Factor (ISF) is the amount you can expect to lower your BG with one unit of insulin. Your health care team may recommend you use different Insulin Sensitivity Factors (ISFs) for different times of the day. When you use the ezCarb or ezBG feature, your pump will automatically select the ISF for the current time stored in the pump.

This screen allows you to set different ISFs for 12 different time slots.

NOTE: If you set only one Insulin Sensitivity Factor, it will be used for the entire 24-hour period.

SETUP ADV 1	
I:C Ratio	
ISF	
BG Target	
Home	<-- -->

1. From the SETUP ADV 1 screen, scroll up to “ISF”. Press **OK**.

2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the **▲/▼** buttons to scroll to the “1U:” (mmol/L) field.

3. Press **OK** to change to flashing cursor for Edit mode.

4. Use the **▲/▼** buttons to change to desired setting.

5. Press **OK** when setting is made.

6. To move to the next ISF screen, scroll to “-->” and press **OK**.

ISF 1 of 12	
Time:	12:00A
1U:	2.3 mmol/L
<<--	-->>
Done	Home

7. Scroll up to the “Time” field and press **OK** to change to flashing cursor for Edit mode.

8. Use the **▲/▼** buttons to change the segment start time. Press **OK**.

9. Scroll to the “1U:” (mmol/L units) field and press **OK** to change to flashing cursor for Edit Mode.

10. Use the **▲/▼** buttons to change the “1U:” (mmol/L units) field as desired. Press **OK**. Repeat to set remaining segments per your health care team’s recommendations.

To review your settings, highlight “**-->>**” and press **OK** to scroll through each segment. Confirm the times and setting values are correct.

When finished, scroll to “Done” and press **OK** to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to “Home” and press **OK**.

ISF 2 of 12	
Time:	6:00A
1U:	2.8 mmol/L
◀--	--▶
Done	Home

Setup Advanced Screen 1 – Personal Settings - BG Target Ranges

A BG Target is your personal goal for keeping your BG levels under control. A BG Target may be set as an actual range (with a minimum and maximum value), or a single value. Your health care team may recommend you use different BG Target ranges (or values) for different times of the day.

The BG Targets (ranges or values) you set in the pump are important as they are used in calculating suggested BG correction bolus amounts when using the ezBG and ezCarb features on your pump (see *Chapter 10* in *Section I*, pages 57-72). When the pump calculates a suggested BG correction bolus, it begins the calculation by determining the difference between your current BG and the BG Target range/value for the current time of day stored in the pump. That number, along with your ISF, is then used to calculate a BG correction bolus amount that would bring your current BG in line with your BG Target range/value.

In addition to the BG correction bolus amount, there are other factors that are used in calculating suggested insulin bolus amounts when using the ezBG and ezCarb features on your pump. These include the amount of Insulin on Board (IOB) from a previous bolus, your ISF, and your I:C Ratio. For more information on IOB including activating the IOB feature on your pump, refer to Setup Advanced Screen 8 – Insulin on Board (IOB) setting on page 53 in this chapter. See *Chapter 10* in *Section I*, pages 57-72 for information on using the ezBG and ezCarb features on your pump.

Before you begin using the ezBG and ezCarb features on your pump, take note how your pump determines the difference between your current BG and the BG Target range/value.

NOTE: The BG Targets discussed here are different than the Low and High Glucose Alerts that apply only to CGM readings. See *Chapter 2* in *Section II*, pages 87-94 for more information on CGM Alerts.

If you set a BG Target range, then the difference between your current BG and your BG Target range is determined as follows:

- If your current BG is above your BG Target range, your pump subtracts the midpoint of your BG Target range from your current BG.

For example, if you set a BG Target range of 5.6–7.8 mmol/L (midpoint is 6.7 mmol/L) and your current BG is 8.9 mmol/L, then the resulting difference is $8.9 \text{ mmol/L} - 6.7 \text{ mmol/L} = 2.2 \text{ mmol/L}$.

- If your current BG is below your BG Target range, your pump subtracts the midpoint of your BG Target range from your current BG. The resulting difference will be a negative number.

For example, if you set a BG Target range of 5.6–7.8 mmol/L (midpoint is 6.7 mmol/L) and your current BG is 4.5 mmol/L, then the resulting difference is $4.5 \text{ mmol/L} - 6.7 \text{ mmol/L} = -2.2 \text{ mmol/L}$.

- If your current BG is within your BG Target range, then the resulting difference is automatically set to 0 mmol/L.

For example, if you set a BG Target range of 4.5–6.1 mmol/L (midpoint is 5.3 mmol/L) and your current BG is 5.0 mmol/L, then the resulting difference is set to 0 mmol/L.

If you set a single BG Target value, then the difference between your current BG and your BG Target value is determined as follows:

- If your current BG is above your BG Target value, the pump subtracts your BG Target value from your current BG.

For example, if you set a BG Target value of 5.8 mmol/L and your current BG is 6.1 mmol/L, then the resulting difference is $6.1 \text{ mmol/L} - 5.8 \text{ mmol/L} = 0.3 \text{ mmol/L}$.

- If your current BG is below your BG Target value, the pump subtracts your BG Target value from your current BG. The resulting difference will be a negative number.

For example, if you set a BG Target value of 5.9 mmol/L and your current BG is 5.6 mmol/L, then the resulting difference is $5.6 \text{ mmol/L} - 5.9 \text{ mmol/L} = -0.3 \text{ mmol/L}$.

- If your current BG is exactly equal to your BG Target value, then the resulting difference is automatically set to 0 mmol/L.

For example, if you set a BG Target value of 5.0 mmol/L and your current BG is 5.0 mmol/L, then the resulting difference is set to 0 mmol/L.

The SETUP ADV 1 (BG Target) screen allows you to set different BG Target (ranges or values) for 12 different time slots. Each BG Target (range or value) is set by first selecting a BG Target and then a +/- amount that will define the minimum and maximum of the range. For example, a BG Target of 6.7 mmol/L and a +/- amount of 0.6 mmol/L means the Target range will be set to 6.1–7.3 mmol/L. If you prefer to correct your BG to one target value rather than a range, set the +/- amount to 0.

SETUP ADV 1	
I:C Ratio	
ISF	
BG Target	
Home	← →

NOTE: If you set only one ratio, it will be used for the entire 24-hour period.

1. From the SETUP ADV 1 screen, scroll up to “BG Target”. Press **OK**.
2. The first segment always starts at midnight. The last time slot available is 11:30pm. Use the **▲/▼** buttons to scroll to the BG Target field.

BG Target 1 of 12	
Time:	12:00A
	6.7 mmol/L
+/-	0.6 mmol/L
◀◀--	--▶▶
Done	Home

3. Press **OK** to change to flashing cursor for Edit mode.
4. Use the **▲/▼** buttons to change to desired setting.
5. Press **OK** when setting is made.
6. Scroll to the “+/-”(range) field. Press **OK** to change to flashing cursor for Edit mode.
7. Use the **▲/▼** buttons to change the range as desired. Press **OK**.
8. To move to the next BG Target screen, scroll to “--▶▶” and press **OK**.
9. Scroll up to the “Time” field and press **OK** to change to flashing cursor for Edit mode.
10. Use the **▲/▼** buttons to change the segment start time. Press **OK**.
11. Scroll to the BG Target field. Press **OK** to change to flashing cursor for Edit mode.
12. Use the **▲/▼** buttons to change to desired setting.
13. Press **OK** when setting is made.
14. Scroll to the “+/-”(range) field. Press **OK** to change to flashing cursor for Edit mode.
15. Use the **▲/▼** buttons to change the range as desired. Press **OK**. Repeat to set remaining segments per your health care team’s recommendations.

BG Target 1 of 12	
Time:	12:00A
	6.7 mmol/L
+/-	0.3 mmol/L
◀◀--	--▶▶
Done	Home

BG Target 2 of 12	
Time:	6:00A
	6.7 mmol/L
+/-	0.6 mmol/L
◀◀--	--▶▶
Done	Home

To review your settings, highlight “--▶▶” and press **OK** to scroll through each segment. Confirm the times and setting values are correct.

When finished, scroll to “Done” and press **OK** to return to the SETUP ADV 1 screen.

To return to the Home screen, scroll to “Home” and press **OK**.

Setup Advanced Screen 2 – Advanced Bolus Features and Multiple Basal Programs

You can program your pump to increase the number of bolus types and basal program options available to you. You can also program the speed of bolus insulin delivery, and choose to turn the personal Reminders feature on or off.

This screen allows you to:

- Turn Advanced Bolus Features (ezCarb, ezBG, Combo Bolus) on or off
- Turn personal Reminders feature on or off
- Select bolus delivery speed (NRML (normal): 1U every second or SLOW: 1U every 5 seconds)

SETUP ADV 2	
BOLUS	
Adv. Bolus	OFF
Reminders	OFF
Delivery	NRML
BASAL	
Programs	4
Home	← →

NOTE: Users may experience a slight stinging sensation with normal bolus delivery. If this occurs changing the bolus delivery speed to “SLOW” may reduce the stinging sensation.

- Select either 1 basal program or 4 basal programs to be displayed in the BASAL MENU

NOTE: If a program other than 1-Weekday is active, you cannot change this setting to display 1 basal program. The Alert screen shown here will be displayed to remind you.

1. From the SETUP ADV 2 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

Alert	
1-weekday must be the active program to change the basal display setting.	
Confirm	

Setup Advanced Screen 3 – Insulin Limits

You can program your pump to control the maximum amount of basal, bolus, daily insulin, and insulin delivered in a 2-hour period. Your pump will alert you when you exceed these amounts.

This screen allows you to:

- Set maximum basal delivery per hour
- Set maximum bolus amount
- Set maximum daily (24-hour) delivery amount. Your pump checks that total insulin delivery each 24-hour period (running from midnight of the previous day to midnight of the current day) does not exceed this limit.
- Set maximum 2-hour delivery amount. Your pump checks that total insulin delivery over each rolling 2-hour period does not exceed this limit.

SETUP ADV 3 Max LIMITS	
Basal	10.00U/Hr
Bolus	35.00U
Daily	200.00U
2Hr	50.00U
Home	← →

1. From the SETUP ADV 3 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

⚠ CAUTION: Should you attempt a delivery that exceeds the limits you have set, your pump will alert you and display a text message. See *Chapter 11 in Section I*, pages 73-84 for additional information.

Setup Advanced Screen 4 – Language Setup, Display Timeout, Contrast and Battery Type

You can customize how information will be displayed on your pump, and what type of battery you will use.

This screen allows you to:

- Select a different language
- Set the length of time your display stays on before timing out to save battery life
 - 15, 30, 45 or 60 seconds
- Select a contrast setting
- Select Lithium (recommended) or Alkaline battery type. If you select the wrong battery type, the alarm screens may not function properly. You can also change the battery type on the VERIFY screen when you insert a new battery.

SETUP ADV 4	
Language	ENGLISH
Display Timeout	in 60 secs
Contrast	8
Battery	Lith
Home	← →

1. From the SETUP ADV 4 screen, scroll to the desired field.

2. Press **OK** to change to flashing cursor for Edit mode.

3. Use the **▲/▼** buttons to change to desired setting.

4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

CONTRAST BUTTON/CGM SHORTCUT

Pressing the button on the top of your pump adjusts the contrast. There are three contrast levels: Dim, Default and Bright. To preserve battery life, your pump display will **Auto-dim** when a button is not pressed for half the time your display time out is set. While in Auto-dim mode, you can restore the default contrast level you have set by pressing the **☉** button on top of your pump. Pressing a function button while in Auto-dim mode will restore the default contrast level as well as perform the function of the key. ***If in Call Service Alarm mode, you must use the ☉ button to restore the default contrast level.***

To return contrast setting to original factory default, press the **▲** button and **☉** button at the same time. When the word “Contrast” is displayed on the screen, press any button to return to the default contrast setting.

NOTE: When viewing your pump display in bright sunlight, it is recommended you shade the screen or move to a shady area for best visibility.

While the pump is in sleep mode, pressing the contrast button/CGM shortcut **☉** will awaken the pump to one of the CGM Data or CGM Trend screens (see *Chapter 6 in Section II*, pages 109-118).

Setup Advanced Screen 5 – Auto-OFF Feature

You may program your pump to automatically suspend basal delivery and sound an alarm if no pump buttons are pressed in a user-selected number of hours. This feature can be used as a safeguard in case the user is unconscious. If the alarm is displayed/sounds, it means all insulin delivery has stopped, and you will need to disconnect the pump and re-prime. See page 83 for more information on the AUTO-OFF Alarm.

⚠ CAUTION: If insulin delivery is suspended because the AUTO-OFF Alarm has sounded/ displayed, your CGM session will remain active, but CGM readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM readings will start recording and displaying again.

This screen allows you to turn the feature on and set the time period for checking if there have been button presses.

1. From the SETUP ADV 5 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

SETUP ADV 5 AUTO OFF	
Enable	OFF
When enabled, suspend in 12 Hr if no buttons are pressed.	
Home	← →

Setup Advanced Screen 6 – Low Cartridge Warning Setting and Occlusion Sensitivity Setting

You can program your pump to alert you when your insulin cartridge is running low. The occlusion detection is automatic. A blockage may restrict the flow of insulin into your body.

This screen allows you to:

- Set your low cartridge warning to alert you at 10, 20, 30, 40 or 50 units remaining in the cartridge
- You can set your pump to detect a blockage with high sensitivity (H) or low sensitivity (L). The sensitivity level refers to how quickly the pump will sense back pressure from an occlusion in the infusion line, with H meaning “more sensitive” and L meaning “less sensitive”. Review the Occlusion Sensitivity setting with your health care team and see page 168 for more information.

1. From the SETUP ADV 6 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

SETUP ADV 6	
Low Cartridge Warning	20U
Occlusion Sensitivity	L
Home	← →

NOTE:

- The Low Cartridge Warning only alerts you one time. For example, if you have it set to 30U and receive an alert, and then change the setting to 20U, it will not alert at 20U until after the next cartridge has been primed.
- If a bolus is delivered which causes a Low Cartridge Warning, your remaining insulin may be less than the Warning screen displays.

Warning	
Low cartridge. 10U or less left.	
Confirm	

Setup Advanced Screen 7 – Audio Bolus Feature

You can set your pump to bolus without having to look at the screen display, by pressing the black button on the right side of your pump. All boluses delivered with the Audio Bolus feature will be delivered as Normal Boluses.

This screen allows you to:

- Turn the Audio Bolus feature on or off
- Select the Audio Bolus delivery step size
 - 0.1, 0.5, 1.0, 5.0 Units

1. From the SETUP ADV 7 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

NOTE: If Audio Bolus is activated, you cannot use the side button as a shortcut to Normal Bolus. You can still give a Normal Bolus via the MAIN MENU.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

SETUP ADV 7 AUDIO BOLUS	
Enable	OFF
Delivery Step	0.1U
Home	← →

Setup Advanced Screen 8 – Insulin on Board (IOB) Setting

The Insulin on Board (IOB) feature activated and set by you helps you calculate how much insulin might still be active in your body from a previous bolus dose. The actual amount of insulin left in your body is determined by the rate at which your body uses insulin, your infusion site, your activity level, and other factors. Your pump uses a curvilinear algorithm that mimics the way insulin is metabolized to track IOB.

The IOB setting is important as IOB amounts are taken into consideration when using the ezBG and ezCarb features on your pump to calculate suggested bolus amounts (see *Chapter 10 in Section I*, pages 57-72). IOB amounts apply only if the feature has been activated on your pump, and you are using either the ezBG or ezCarb features to calculate a suggested bolus amount. In certain situations, your pump will calculate a reduced suggested total bolus amount to account for any IOB.

IOB when using the ezCarb feature:

The ezCarb Bolus Total screen will display a carb correction amount, a BG correction amount, your IOB amount (if the feature is activated), and a suggested total bolus amount.

NOTE: The displayed carb correction, BG correction, and IOB amounts (if the feature is activated), and the resulting total bolus amount are for reference only. They do not represent the actual calculation performed on the pump.

If the IOB feature is activated, your IOB amount will always be displayed for reference, but may not always be applied to the suggested total bolus amount.

Refer to *Chapter 10 in Section I*, page 64 for an example of ezCarb when the IOB feature on your pump is activated.

IOB when using the ezBG feature:

The ezBG Total screen will display a BG correction amount, your IOB amount (if the feature is activated), and a suggested total bolus amount.

NOTE: The displayed BG correction and IOB amounts, and the resulting total bolus amount are for reference only. They do not represent the actual calculation performed on the pump.

If the IOB feature is activated, your IOB amount will always be displayed for reference, but may not always be applied to the suggested total bolus amount. For instance, when IOB is enough to cover the amount required to bring a high BG back into target range, no additional insulin amount will be suggested to cover the high BG.

Refer to *Chapter 10 in Section I*, page 67 for an example of ezBG when the IOB feature on your pump is activated.

⚠ WARNING: The IOB feature is intended for use only with U100 rapid-acting insulin analogs such as Novo Rapid®, NovoLog®, Humalog®, or Apidra®. If you use an insulin other than Novo Rapid®, Novolog®, HumaLog®, or Apidra®, Do Not use this feature. Use of any insulin with lesser or greater concentration can result in serious injury or death.

Then SETUP ADV 8 screen allows you to:

- Turn the IOB feature on or off
- Select the duration from 1.5 to 6.5 hours in half-hour increments.

1. From the SETUP ADV 8 screen, scroll to the desired field.

2. Press **OK** to change to flashing cursor for Edit mode.

3. Use the **▲/▼** buttons to change to desired setting.

4. Press **OK** when setting is made.

SETUP ADV 8 Insulin on Board	
IOB-2	OFF
Duration 4.0 Hr	
Home	← →

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

NOTE: Your pump is constantly tracking IOB, so when you turn on the feature, your pump will immediately take into account the current amount remaining from previous bolus doses within the time frame you have selected during set up of the feature.

Setup Advanced Screen 9 – Sick Day Guidelines

During your pump training, your health care team will discuss guidelines to use when you are sick, such as when to test your BG or ketones. Your pump provides a convenient way to store some of these guidelines. For more information on sick day guidelines, refer to *Chapter 4 in Section III*, pages 157-158, and contact your health care team.

This screen allows you to:

- Set a BG limit as a reminder for testing when sick
- Set the frequency of checking for ketones when sick
- Set the frequency of checking your BG when sick

SETUP ADV 9 Sick Days	
BG over	13.3 mmol/L
Check ketones every	4 Hrs
Check BG every	2 Hrs
Home	← →

1. From the SETUP ADV 9 screen, scroll to the desired field.
2. Press **OK** to change to flashing cursor for Edit mode.
3. Use the **▲/▼** buttons to change to desired setting.
4. Press **OK** when setting is made.

To move to the next Setup Advanced screen, scroll to the bottom of the screen and highlight “→”. Press **OK**.

To return to the Home screen, scroll to “Home” and press **OK**.

NOTE:

- This screen is intended as a reference only. Alerts are NOT triggered based on values displayed on this screen.
- The BG limit you set on the SETUP ADV 9 screen is different than the Low and High Glucose Alerts that apply only to CGM readings. See *Chapter 2 in Section II*, pages 87-94 for more information on CGM Alerts.

⚠ CAUTION: Using the features in this chapter requires an advanced understanding of insulin pump therapy and should not be used without training and advice from your health care team. In order to achieve optimal results, some of these features should only be used once you have tested and fine-tuned your basal rates and your health care team has determined your individual targets and ratios.

NOTE: Before using these features, you must turn them on in the Setup Advanced menu. See *Chapter 9 in Section I*, pages 43-56.

Audio Bolus/ezBolus™ Button

The Audio Bolus/ezBolus™ button on the right side of your pump serves two purposes. If you activate the Audio Bolus feature, it allows you to bolus without looking at the screen display. This is convenient if you wear your pump under your clothing. When first using the Audio Bolus feature, also check the display screen until you are comfortable with the programming steps. If you do not wish to use the Audio Bolus feature, this button serves as a shortcut to the Normal Bolus screen. See *ezBolus™*, page 59 in this chapter.

⚠ CAUTION: When you first use the Audio Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with the feature.

1. Turn on Audio Bolus in the Setup Advanced menu and select your preferred step size. See *Chapter 9 in Section I*, pages 43-56.

2. The Audio Bolus button is the soft rubber button on the end of your pump. Press it once. Your pump will beep (or vibrate) to indicate you have accessed Audio Bolus mode as well as indicate the step size you have set up.

The number of beeps (or vibrate pulses) reminds you of the step size you have set.

- 1 beep (or vibration pulse) indicates 0.1U step size
- 2 beeps (or vibration pulses) indicates 0.5U step size
- 3 beeps (or vibration pulses) indicates 1.0U step size
- 4 beeps (or vibration pulses) indicates 5.0U step size

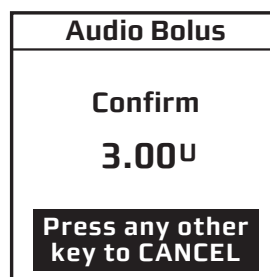
3. Press the Audio Bolus button once for each step size you have programmed to reach the desired total amount. For example, if you are using 1.0U step size and you wish to bolus 4 units, press the button 4 times. You will hear a beep tone or vibrate for each button press. If you are using 0.5U step size and you wish to bolus 4 units, press the button 8 times.

4. Within 5 seconds, your pump will respond with a number of confirmation beeps equal to the number of times you pressed the Audio Bolus button.

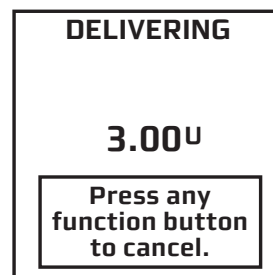
NOTE: Do Not press any of the function buttons at this time unless you wish to cancel delivery.

Audio Bolus Step size= 1.0U/Press
Enter bolus amount 0.00U
Press any other key to CANCEL

5. Within 5 seconds, your pump will beep twice to “ask” you to confirm that you wish to activate delivery and “Confirm” is displayed on the Audio Bolus screen.

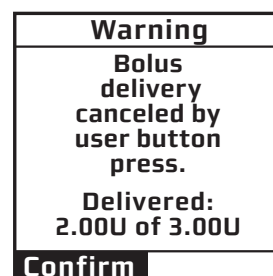


6. Within 5 seconds, press the button again to activate delivery. Your pump will beep twice to confirm your delivery command. The DELIVERING bolus screen is displayed and your pump will beep once to signal the start of delivery and once to signal end of delivery (if you turned on Normal Bolus Sounds in Setup).



If you wish to cancel the Audio Bolus, press any function button.

If you cancel a bolus delivery after you have activated it, the screen at right will be displayed. See *Chapter 11 in Section I*, pages 73-84.



NOTE: If during a bolus delivery your low cartridge level is reached, your pump will not display the warning until after the bolus is completed. So you could possibly have less insulin available than your low cartridge setting.

The maximum number of Audio Bolus button presses is 20. Therefore, if you have set the step size to 0.1U, the maximum audio bolus amount is 2U. If you have set the step size at 0.5U, the maximum audio bolus amount is 10U and if your step size is 1.0U, the maximum audio bolus amount is 20U. With a 5.0U step size, the maximum cannot be greater than 35U, which is the maximum amount for any type of bolus.

ezBolus™

ezBolus™ is a one-button shortcut to the Normal Bolus screen whenever the Audio Bolus feature is not activated.

1. Press the black button on the right side of your pump once. The Normal Bolus screen is displayed. Program a Normal Bolus as usual.

NORMAL BOLUS
Amount 0.00 u
Go Main Menu

Advanced Bolus Features

- ezCarb
- ezBG
- Combo Bolus
- Reminders

All Advanced Bolus features are activated in the Setup Advanced Menu. See *Chapter 9* in *Section I*, pages 43-56. When the Advanced Bolus features and Reminders are activated, the full BOLUS MENU is displayed.

BOLUS MENU
Normal ezCarb ezBG Combo Bolus Reminders
Main Menu

⚠ WARNING: Be sure to review all the values used in bolus calculations to make sure they are correct. You may always adjust the insulin units up or down before you decide to administer your bolus. If you dose an insulin amount that is too high or too low, this may result in a hypoglycemic or hyperglycemic event. Please discuss the bolus calculator feature and all relevant personal settings with your health care professional before using the calculator for the first time.

NOTE: When using the ezCarb or ezBG feature to calculate a “suggested” total bolus amount, that amount will be set to 0.00U whenever the calculation results in a negative number.

ezCarb

This feature allows you to enter the number of carbs eaten. Your pump will then automatically calculate your bolus dose, based on your I:C ratio, ISF and BG Target for the current time stored in the pump. Consult your health care team for your personal I:C ratios, ISFs and BG Target ranges. See *Chapter 9* in *Section I*, pages 43-56.

If the IOB feature is activated, your pump will take IOB amounts into consideration when calculating a suggested bolus amount. If the IOB feature is not activated on your pump, dashes (---) will appear instead of a number in the “IOB” field.

The following pages provide examples of how to use the ezCarb feature to calculate a suggested bolus amount to cover a set number of carbs and reduce a high BG. The first example shows how to calculate a carb bolus. The second example shows how to add a BG correction bolus to a carb bolus.

NOTE: Carb amounts you enter with the ezCarb feature will be stored in the pump along with insulin delivery data. You can use Diasend® Web-based Diabetes Management System to track, review and analyze pump carb and insulin data on your computer. Visit www.diasend.com/animas for more information.

Calculating an ezCarb Bolus

1. From the BOLUS MENU, scroll to “ezCarb”. Press **OK**. The ezCarb Home screen is displayed.

BOLUS MENU	
Normal	
ezCarb	
ezBG	
Combo Bolus	
Reminders	
Main Menu	

2. The cursor will flash on the “Carbs” field to indicate that you can edit the total number of carbs eaten. Use the **▲/▼** buttons to enter the number of carbs. Press **OK**. “Add BG” is highlighted. (See *Adding a BG Bolus to ezCarb*, page 62 in this chapter.)

ezCarb Home	
Carbs:	34g
[Actual	0g]
I:C	1U: 15g
Food List	
Review Total	
Add BG	
Show Result	
Main Menu	

NOTE:

- The max limit for carb totals that are used in the bolus calculator is 999g.
- The “Actual” field below the “Carbs” field will be set to 0g (grams). This refers to carb amounts that are entered from the “Food List” option, which is not yet operational with the Animas® Vibe™ Insulin Pump you received with this Owner’s Booklet.

3. Check that the grams of carb entered and your I:C ratio at the top of the screen are correct.

a. If the entries are *correct*, scroll to “Show Result”. Press **OK** and go to Step 5.

b. If *not correct*, scroll up to highlight the field and press **OK** to activate Edit Mode. Use **▲/▼** buttons to enter your I:C ratio and/or change the carb entry. Press **OK**.

ezCarb Home	
Carbs:	34g
[Actual	0g]
I:C	1U: 15g
Food List	
Review Total	
Add BG	
Show Result	
Main Menu	

4. Scroll down to “Show Result”. Press **OK**.

5. The Bolus Total screen is displayed and the suggested (calculated) bolus amount from your ezCarb Bolus appears in the “Total” field. Above the “Total” field are the three parts that are used in calculating the suggested “Total” amount. **Carb** refers to the carb correction amount that was calculated to cover the carbs you manually entered. **BG** refers to any BG correction bolus you may have added. In this example, you did not add a BG correction so the BG amount is set to 0.00U. **IOB** refers to the IOB amount from a previous bolus. In this example, the IOB feature is not turned on so dashes appear instead of a number.

Bolus Total	
Carb	2.26U
BG +	0.00U
IOB	--- U
Total =	2.25U
Go	0.00U
Type	Normal
Main Menu	

Below the suggested “Total” amount is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing.

Press the  button once to change the amount to match the suggested bolus amount. Then use the  buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press .

NOTE:

- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested “Total” bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested “Total” amount) when you press the  button once.

Bolus Total	
Carb	2.26U
BG +	0.00U
IOB	--- U
Total =	2.25U
Go	2.25U
Type	Normal
Main Menu	

6. “Go” is highlighted. If you wish to give a Normal Bolus, press  to deliver.

Bolus Total	
Carb	2.26U
BG +	0.00U
IOB	--- U
Total =	2.25U
Go	2.25U
Type	Normal
Main Menu	

DELIVERING	
2.25U	
Press any function button to cancel.	

7. If you wish to give a Combo Bolus, scroll to the “Type” field and press  to edit.

8. Use the  buttons to select bolus type: “Normal” (default) or “Combo”. Press .

Bolus Total	
Carb	2.26U
BG +	0.00U
IOB	--- U
Total =	2.25U
Go	2.25U
Type	Combo
Main Menu	

9. “Go” is highlighted. Press .

NOTE: If you select the Combo Bolus option, the Combo Bolus screen will be displayed. See *Combo Bolus*, pages 68-69 in this chapter for instructions on delivering the Combo Bolus.

Adding a BG Correction Bolus to ezCarb

The following example shows how to add a BG correction bolus to a carb bolus.

1. On the ezCarb Home screen, enter the number of carbs. Press **OK**.
2. “Add BG” is highlighted. Press **OK**. The BG CORRECT screen is displayed.

NOTE:

- **Do Not** enter CGM readings as BG values. CGM readings should never be used to make insulin dosing or other treatment decisions. Always verify BG levels with a BG meter.
- The Food List option on ezCarb Home screen is not yet operational with the Animas® Vibe™ Insulin Pump you received with this Owner’s Booklet.

ezCarb Home	
Carbs:	34g
[Actual	0g]
I:C	1U:
15g	
Food List	
Review Total	
Add BG	
Show Result	
Main Menu	

3. The “Actual” field is highlighted and flashing to indicate Edit mode. Use the **▲/▼** buttons to enter your current (Active) BG value. Press **OK**. “Show Result” is highlighted.

BG CORRECT	
	mmol/L
Actual	12.2
Target	- 6.7
	= + 5.6
ISF	2.1 mmol/L
Show Result	
Main Menu	

BG CORRECT	
	mmol/L
Actual	12.2
Target	- 6.7
	= + 5.6
ISF	2.1 mmol/L
Show Result	
Main Menu	

4. Check that the BG Target and ISF are correct.

- a. If they are *correct*, press **OK** with “Show Result” highlighted.
- b. If they are *not correct*, scroll up to highlight the fields and press **OK**. Use the **▲/▼** buttons to adjust the values. Press **OK** to exit Edit mode. Scroll down to “Show Result”. Press **OK**.

BG CORRECT	
	mmol/L
Actual	12.2
Target	- 6.7
	= + 5.6
ISF	2.1 mmol/L
Show Result	
Main Menu	

BG CORRECT	
	mmol/L
Actual	12.2
Target	- 6.7
	= + 5.6
ISF	2.1 mmol/L
Show Result	
Main Menu	

5. The Bolus Total screen is displayed and the suggested (calculated) bolus amount from your ezCarb Bolus appears in the “Total” field. Above the “Total” field are the three parts that are used in calculating the “Total” suggested amount. **Carb** refers to the carb correction amount. **BG** refers to the BG correction amount calculated from the BG CORRECT screen. **IOB** refers to the IOB amount from previous bolus. In this example, the IOB feature is not turned on.

Bolus Total	
Carb	2.26U
BG +	2.70U
IOB	--- U
Total =	4.95U
	0.00U
Go	
Type	Normal
Main Menu	

Below the suggested “Total” amount is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing. Press the  button once to change the amount to match the suggested bolus amount. Then use the  buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press .

NOTE:

- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested “Total” bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested “Total” amount) when you press the .

6. “Go” is highlighted. Press  to deliver as a Normal Bolus or scroll to the “Type” field to select Combo Bolus, then select “Go”.

If you selected the Combo Bolus option, you will begin the steps for delivering the ezCarb units as a Combo Bolus (see *Combo Bolus*, pages 68-69 in this chapter). The bolus amount you entered on the Bolus Total screen in step 6 will appear in the “Total” field on the first Combo Bolus screen.

Bolus Total	
Carb	2.26U
BG +	2.70U
IOB	--- U
Total =	4.95U
	4.95U
Go	
Type	Normal
Main Menu	

7. After the bolus is delivered, you will be prompted on the display to decide if the BG value you just entered should be used to calibrate your CGM (see *Chapter 5 in Section II*, pages 105-108). Select “YES” and press  to use this BG value for CGM calibration.

NOTE:

- This screen will appear only if you are in an active CGM session. If you decide to use the BG value for CGM calibration, the value must be within 2.2–22.2 mmol/L, must be from a fingerstick BG test, and must have been taken within the last 5 minutes. **Do Not** use a BG test result from an alternative sampling site (e.g., palm or forearm) for CGM calibration.
- The pump display may time out before you have had a chance to confirm the use of the BG value for CGM calibration. In this case, the BG value will **not** be used for CGM calibration.

Use BG For CGM Calibration? Must Be A Fingerstick	
YES	NO

ezCarb Examples with the IOB Feature Activated

If the IOB feature is activated, your IOB amount will be displayed for reference on the ezCarb Bolus Total screen.

With the IOB feature activated, your suggested ezCarb total bolus amount will be as follows:

- If your current BG is above your target range, and your BG correction amount is greater than your IOB amount, then your suggested total bolus amount will be your Carb correction amount plus your BG correction amount minus your IOB amount. This is illustrated in example 2 that follows.
- If your current BG is above your target range, and your IOB amount is greater than your BG correction amount, then your suggested total bolus amount will be your Carb Correction amount. This is illustrated in example 1 that follows.
- If your current BG is within your target range, or equal to your target value, your suggested total bolus amount will be your Carb correction.
- If your current BG is below your target range, your suggested total bolus amount will be your Carb correction amount plus your BG correction amount minus your IOB amount. The suggested total bolus amount will be 0.00U whenever the calculation results in a negative number. A negative number implies that any additional insulin bolus amount would potentially result in over delivery of insulin and hypoglycemia. Discuss the calculator feature with your health care professional so you have a thorough understanding of how it works before you begin using it.

The following examples illustrate typical screens you may encounter when using the ezCarb feature with IOB activated.

Bolus Total	
Carb	2.26U
BG +	2.70U
IOB -	3.00U
Total =	2.25U
	0.00U
Go	
Type	Normal
Main Menu	

Example 1

In Example 1, the IOB amount is displayed for reference but is not applied to the suggested total bolus amount. In this case, even though your current BG level is above the target range, there is sufficient IOB to cover the high BG. Therefore, the only insulin amount suggested is to cover the carbs being consumed.

Bolus Total	
Carb	2.26U
BG +	2.70U
IOB -	1.00U
Total =	3.95U
	0.00U
Go	
Type	Normal
Main Menu	

Example 2

In Example 2, the IOB amount is displayed for reference and is applied to the suggested total bolus amount. In this case, your current BG is above your target range, and your BG correction amount is greater than your IOB amount. Therefore, the insulin amount suggested is to cover the carbs being consumed, and any BG correction amount not already covered by your IOB.

Bolus Total	
Carb	2.26U
BG -	1.00U
IOB -	0.50U
Total =	0.75U
	0.00U
Go	
Type	Normal
Main Menu	

Example 3

In Example 3, your current BG is below your target range, resulting in a negative BG correction amount. In this case, your carb amount needs to be offset by your BG correction amount since you are already below your target range. Therefore, the insulin amount suggested is to cover only the carb amount not already covered by your IOB amount and the negative BG correction amount.

ezBG

This feature allows you to enter your current (Actual) BG value and your pump will automatically calculate a BG correction bolus based on your ISF and BG Target range for the current time stored in the pump. If the IOB feature is activated, your pump will subtract your IOB amount from the BG correction amount before calculating and displaying the suggested bolus amount.

1. From the BOLUS MENU, select “ezBG”. Press the **OK** button.

BOLUS MENU	
Normal	
ezCarb	
ezBG	
Combo Bolus	
Reminders	
Main Menu	

2. The “Actual” field will be highlighted and flashing to indicate Edit mode. Use the **▲/▼** buttons to enter your actual BG value. Press the **OK** button to confirm the entry and exit Edit mode.

NOTE: Do Not enter CGM readings as BG values. CGM readings should never be used to make insulin dosing or other treatment decisions. Always verify BG levels with a fingerstick test from your BG meter.

ezBG	
	mmol/L
Actual	12.4
Target	- 6.7
	= + 5.8
ISF	2.1 mmol/L
Show Result	
Main Menu	

ezBG	
	mmol/L
Actual	12.4
Target	- 6.7
	= + 5.8
ISF	2.1 mmol/L
Show Result	
Main Menu	

The difference between your current (Actual) BG and BG Target appears below the “Target” field. The difference is calculated according to whether your current (Actual) BG is within, below, or above your BG Target. Refer to Setup Advanced Screen1 – BG Target Ranges in *Chapter 9* in *Section I*, pages 43-56, for information on how your BG Target settings impact the calculation of a BG correction bolus.

3. Check to be sure the BG Target and Insulin Sensitivity Factor (ISF) are correct. Your health care team will give you these values. If you need to edit these fields, scroll up to highlight the field and press **OK** to activate Edit mode. Use **▲/▼** buttons to change target. Press **OK** to confirm and to exit Edit mode.

ezBG	
	mmol/L
Actual	12.4
Target	- 6.7
	= + 5.8
ISF	2.1 mmol/L
Show Result	
Main Menu	

4. “Show Result” is highlighted. Press **OK**.

ezBG	
	mmol/L
Actual	12.4
Target	- 6.7
	= + 5.8
ISF	2.1 mmol/L
Show Result	
Main Menu	

CHAPTER 10 - USING ADVANCED FEATURES

5. The ezBG Total screen is displayed and the suggested bolus amount from your ezBG Bolus appears in the “Total” field. Above the “Total” field are the two parts that are used in calculating the suggested “Total” amount. **BG** refers to the BG correction amount calculated from the previous ezBG screen. **IOB** refers to the IOB amount from a previous bolus.

ezBG Total		
BG	+	2.81U
IOB		--.-- U
Total	=	2.80U
		0.00U
Go		
Main Menu		

Below the suggested amount “Total” is the bolus amount entry field where you can choose to deliver the suggested amount or adjust the amount as needed. This field will display 0.00U, and will be highlighted and flashing. Press the  button once to change the amount to match the suggested bolus amount. Then use the / buttons to adjust the amount if necessary. When you have the desired delivery amount displayed, press . With “Go” highlighted, press  to deliver the bolus.

ezBG Total		
BG	+	2.81U
IOB		--.-- U
Total	=	2.80U
		2.80U
Go		
Main Menu		

NOTE:

- If the BG amount on the ezBG Total screen is a negative number, the suggested “Total” amount will be set to 0.00U.
- Calculated total units will be rounded to the nearest .05 units.
- If the maximum bolus limit you set in Advanced Features is less than the suggested “Total” bolus amount on the Bolus Total screen, the bolus amount entry field will change to that limit (rather than the suggested “Total” amount) when you press the  button once.

DELIVERING	
2.80U	
Press any function button to cancel.	

6. After the bolus is delivered, you will be prompted on the display to decide if the BG value you just entered should be used to calibrate your CGM (see *Chapter 5* in *Section II*, pages 105-108). Select “YES” and press  to use this BG value for CGM calibration. If the pump display times out before you select “Yes”, the BG value will **not** be used for CGM calibration.

Use BG For CGM Calibration? Must Be A Fingerstick	
YES	NO

NOTE:

- If you enter a BG amount below 3.9 mmol/L or above 13.9 mmol/L, your pump will alert you that you have entered an out of range BG. To confirm the Alert, press . Your pump will still use the out of range BG value in ezCarb and ezBG bolus calculations, but treat the out of range BG as recommended by your health care team.

Alert	
LOW BG Treat low BG. No bolus recommended. Monitor BG.	
Confirm	

Alert	
HIGH BG Treat high BG. Check site. Check ketones. Monitor BG.	
Confirm	

- The LOW BG and HIGH BG Alerts discussed here are different than the Low and High Glucose Alerts that apply only to CGM readings. See *Chapter 2* in *Section II*, pages 87-94 for more information on CGM Alerts.

ezBG Examples with the IOB Feature Activated

If the IOB feature is activated, your IOB amount will be displayed for reference on the ezBG Total screen.

With the IOB feature activated, your suggested ezBG total bolus amount will be as follows:

- If your current BG is above your target range, and your BG correction amount is greater than your IOB amount, the suggested total bolus will be your BG correction amount minus your IOB amount. This is illustrated in example 1 below.
- In all other situations, your suggested total bolus will be 0.00U.

The following examples illustrate typical screens you may encounter when using the ezBG feature with IOB activated.

ezBG Total		
BG	+	2.81U
IOB	-	1.00U
Total	=	1.80U
		0.00U
Go		
Main Menu		

Example 1

In Example 1, the IOB amount is displayed for reference and is applied to the suggested total bolus amount.

ezBG Total		
BG	+	0.00U
IOB	-	1.00U
Total	=	0.00U
		0.00U
Go		
Main Menu		

Example 2

ezBG Total		
BG	+	1.50U
IOB	-	2.00U
Total	=	0.00U
		0.00U
Go		
Main Menu		

Example 3

In Examples 2 and 3, the IOB amount is displayed for reference but is not applied to the suggested total bolus amount. In both cases, even though your current BG level is above the target range, there is sufficient IOB to cover the high BG. Therefore, no insulin amount is suggested to cover the high BG.

Combo Bolus

The Combo Bolus feature is used to “split” your bolus into a Normal and Extended Bolus. This feature is useful for consumption of high carb/high fat meals such as pizza, that have prolonged carb absorption. It is also useful if you will be eating (“grazing”) over a few hours or if you have gastroparesis, where food remains in the stomach for a longer period than normal. You can program part of your bolus amount to be delivered immediately (Normal portion) and part of it to be delivered slowly over the course of up to 12 hours (Extended portion). Your health care team can help you determine the “split” of Normal to Extended insulin amounts, as well as the duration that is most appropriate for you.

BOLUS MENU	
Normal	
ezCarb	
ezBG	
Combo Bolus	
Reminders	
Main Menu	

1. From the BOLUS MENU, select “Combo Bolus”. If you used the ezCarb Bolus option to calculate a bolus and chose to deliver it as a Combo Bolus, you will begin at the Combo Bolus screen in step 2.

2. Use the ▲/▼ buttons to enter the Total bolus amount. Press **OK**. “Go” is highlighted. The factory default setting for Duration is 30 minutes, and the Ratio is 0% Normal and 100% Extended. If these settings are appropriate, press **OK** to deliver.

Combo Bolus	
Total	8.50U
Duration	0.5Hr
Normal: Extend	
0: 100%	
0.00: 0.00U	
Go	
Main Menu	

Combo Bolus	
Total	8.50U
Duration	4.0Hr
Normal: Extend	
30: 70%	
2.55: 5.95U	
Go	
Main Menu	

3. To change either the Duration or Ratio, scroll up to the desired field and press **OK** to activate Edit mode.

4. Use the ▲/▼ buttons to change settings. As you change the Ratio by percentage, the amount in units is automatically changed. *You cannot change the ratio by units, only by percentage.*

Combo Bolus	
Total	8.50U
Duration	0.5Hr
Normal: Extend	
30: 70%	
2.55: 5.95U	
Go	
Main Menu	

5. When settings are correct, press **OK** to confirm and exit Edit Mode.

NOTE: Your pump is “smart”; it will remember your last duration and the ratio (as percentages) you programmed. So if you use the same duration and ratio for certain types of meals, you need only change the total bolus amount the next time you use this feature. However, the last programmed Combo Bolus settings will be cleared each time you change the battery.

6. Scroll to “Go” and press **OK** to activate. The Home screen shows Combo Bolus Active.

Combo Bolus	
Total	8.50U
Duration	4.0Hr
Normal: Extend	
30: 70%	
2.55: 5.95U	
Go	
Main Menu	

2:27 ^{PM}	
	
BOLUS ACTIVE	
Basal Rate	
0.675U/Hr	
Insulin: 105U	
Status	Menu

Combo Bolus ACTIVE	
Duration	0.0 : 4.0Hrs
Delivered	2.55U : 8.50U
CANCEL	
Main Menu	

To *cancel* an active Combo Bolus from the BOLUS MENU, select “Combo Bolus”. Details of the active Combo Bolus will be displayed.

Scroll to “CANCEL” and press **OK** to cancel the Combo Bolus.

NOTE: If you Suspend your pump, any active Combo Bolus will also be canceled and the screen display will alert you. Combo Bolus is also canceled when you change the battery and/or prime your pump.

Reminders

This feature allows you to set personal reminders if you have activated the Reminders feature (see *Setup Advanced Screen 2* in *Chapter 9* in *Section I*, page 48). You can set two separate reminders to prompt you at two designated times during the day, and one reminder to check BG at a certain time after a bolus. Confirm the Reminder by pressing **OK**. Once you have confirmed the Reminder, you will not be alerted again.

Bolus Reminders for Time of Day

BOLUS MENU	
Normal	
ezCarb	
ezBG	
Combo Bolus	
Reminders	
Main Menu	

1. From the BOLUS MENU, select “Reminders”. Press **OK**.

2. The “Reminder-1” field will be highlighted with a flashing cursor to indicate Edit mode. Use the **▲/▼** buttons to turn on or off. Press **OK** to confirm and exit Edit mode.

REMINDERS	
Reminder-1	OFF
Time =	12:00AM
Reminder-2	OFF
Time =	12:00AM
BG Check	OFF
After Bolus =	1 Hr
Main Menu	

3. The “Time” field for this reminder will be highlighted. Press **OK** to activate Edit mode. Use the **▲/▼** buttons to enter the time you wish a reminder to sound (or vibrate, if that is the setting you selected in the SETUP SOUND menu). Press **OK** to confirm your setting and exit Edit mode.

REMINDERS	
Reminder-1	OFF
Time =	12:00AM
Reminder-2	OFF
Time =	12:00AM
BG Check	OFF
After Bolus =	1 Hr
Main Menu	

When the feature is turned on, your pump will display the “Reminder” screen on the right at the selected time of day.

4. Repeat for Reminder 2.

Reminder	
12:00AM	
Confirm	

BG Check Reminder

REMINDERS	
Reminder-1	OFF
Time =	12:00AM
Reminder-2	OFF
Time =	12:00AM
BG Check	OFF
After Bolus =	1 Hr
Main Menu	

1. From the REMINDERS menu, select “BG Check” to remind you to check your BG. Press **OK** to activate Edit mode to turn this reminder on or off. Press **OK** to confirm and exit Edit mode.

NOTE: The BG Check reminder you set here is independent of the “Enter BG” prompts you will see when using your pump with the CGM (see *Section II*, pages 85-140).

2. Scroll down to highlight the “After Bolus” field. Press **OK** to select the field and activate Edit mode. Use the **▲/▼** buttons to enter how long after a Normal Bolus you wish your pump to sound (or vibrate) to remind you to check your BG. You can select a reminder time of 1, 2, 3 or 4 hours.

REMINDERS	
Reminder-1	OFF
Time =	12:00AM
Reminder-2	OFF
Time =	12:00AM
BG Check	ON
After Bolus =	1Hr
Main Menu	

BG Reminder	
Check BG in 1 Hr	
Confirm	

When this feature is turned on, your pump will display the BG Reminder screen immediately after a bolus. On this screen you can use the **▲/▼** buttons to select a different reminder time (1, 2, 3, or 4 hours), or choose not to be reminded by entering 0. For example, if you have given a bolus in the evening, you may not wish to have the Reminder sound while you are sleeping. If the Reminder is not confirmed, battery life will be reduced and the Replace Battery Alarm will appear sooner than expected.

NOTE: The BG Reminder screen is not displayed when you use the Audio Bolus feature.

NOTE: When you enter a time, your pump will sound a reminder and display this screen at that time after any Normal Bolus or Audio Bolus is delivered, including the Normal portion of a Combo Bolus. If you program an Extended Bolus only, the reminder will sound at the default time you have set.

3. When finished setting reminders, scroll to “Main Menu” and press **OK** to display the MAIN MENU.

Reminder Check BG Last bolus 12:15PM Confirm

Delivery Speed – Bolus

On rare occasions, usually with very large boluses, users may experience a slight stinging sensation with rapid bolus delivery. If this is a concern, you can set the bolus delivery speed to slow to accommodate your needs. If you use the slow setting, your pump will pause approximately 4 seconds in between delivery of each unit of insulin programmed.

Multiple Basal Programs

This feature allows 4 different Basal programs to show on your BASAL MENU screen. Users find this feature beneficial if their activity level is different during the week than on weekends. Switching work shifts at work is another reason to use multiple basal programs. Some use a different basal program during menstruation. An “A” will appear to the left of the Basal program that is currently active.

BASAL MENU	
Total	13.60U
Temp	
A1-WEEKDAY	
2-other	
3-weekend	
4-exercise	
Main Menu	

NOTE: If a program other than 1-Weekday is active, you cannot change this setting to display 1 basal program. The Alert screen shown here will pop up to remind you.

Alert
1-weekday must be the active program to change the basal display setting.
Confirm

IOB

Your pump constantly tracks IOB, even if you have not activated the IOB feature. If you have given a bolus and then activate the IOB feature, your pump will show the remaining amount from that bolus as IOB on ezCarb and ezBG calculator screens.

NOTE:

- When you replace the battery, the IOB amount is cleared.

Sick Day Guidelines

To review your basic sick day guidelines, refer to this screen. For more information on sick day guidelines, refer to *Chapter 4* in *Section III*, pages 157-158, and contact your health care team.

1. From the SETUP menu, select “Advanced”.
2. Scroll to the Setup Advanced Screen 9.
3. Enter or review the guidelines as recommended by your health care team.

SETUP ADV 9 Sick Days	
BG over	13.3 mmol/L
Check ketones every	4 Hrs
Check BG every	2 Hrs
Home	← →

Alerts, Warnings and Alarms

Your pump has a “progressive” warnings and alarms safety system. This means if you do not confirm the warning or alarm, it will get progressively louder and change to a sweep tone with vibrate within one hour. At the high volume stage, if you do not confirm the warning or alarm, the sweep tone will begin and will not stop until appropriate action is taken.

NOTE: Your pump uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your pump will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.

Additionally, certain warnings (e.g., Low Cartridge Warning, Occlusion Alarm) take precedence over less critical ones (e.g., Low Battery Warning). This means if you do not confirm the more critical warning, battery life will be reduced and your pump may skip the Low Battery Warning and go directly to the Replace Battery Alarm.

If multiple alerts, warnings, or alarms occur simultaneously, the pump will display the most critical one first. After confirming the condition with the highest priority (the one currently displayed), the alert, alarm, or warning with the next highest priority will be displayed until confirmed. Each alert, alarm, and/or warning must be confirmed separately until all simultaneous conditions have been confirmed.

Take special note of alerts, alarms and/or warnings that include messages about insulin delivery continuing or stopping, particularly when they occur simultaneously on the pump. It is possible to see a “Deliveries continue” message followed by a “No delivery” message. “Deliveries continue” means insulin delivery is not impacted by the alert, alarm and/or warning that prompted the message. “No delivery” means insulin delivery has stopped and will remain stopped until the problem that caused the alert, alarm and/or warning to appear is resolved.

Alerts are automatically displayed to remind you of a function that you have set or a condition that exists. Warnings are triggered for a variety of reasons. They require you to confirm the warning by pressing **OK** and/or taking action to address the warning. Alarms are triggered by several conditions. All require you to address the alarm by taking appropriate action in order to clear the alarm condition.

🎵 – Indicates that this alert, warning or alarm can play a tune as the initial notification for medium and high volume settings. The pump default for sounds at the low volume setting is a factory-set sound.

There is an additional list of warnings, alarms and alerts that will display/sound on your pump related to the use of CGM functions when you begin using your CGM with your pump. See *Chapter 10* in *Section II*, pages 127-140 for more information on this list.

NOTE: Alarms, warnings and alerts will display actual insulin units during pump operation, rather than the “XX” or “XXX” units displayed on some of the screens in this list.

Alerts, Warnings and Alarms

Alert: Active Basal Program Empty	
Cause	Active basal program is empty.
Effect	No basal deliveries.
Message	Displayed once until confirmed or until pump goes to sleep and each time manually awakened.
Action	None required but can confirm or select Basal Menu.
Beeps/Vib	User selected, one time and each time manually awakened. No progression.

Alert
Your active basal program is empty. 0.000U/Hr
Confirm Basal Menu

Alert: Temp Basal Minimum Rate	
Cause	Negative Temp Basal activated.
Effect	Basal delivery will not go below 0.025U/Hr.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected, one time. No progression.

Alert
Temp Active Minimum Basal rate limited to 0.025U/Hr

Alert: Suspend (Temp Basal/Combo Bolus Canceled)	
Cause	Pump suspended.
Effect	Any active Temp Basal/Combo Bolus canceled.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected, one time. No progression.

Alert
Pump Suspended
If active, Temp Basal & Combo Bolus have been canceled.

Alerts, Warnings and Alarms

Alert: Low BG 	
Cause	BG entry below 3.9 mmol/L.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press  to confirm.
Beeps/Vib	User selected, one time. No progression.
NOTE: The LOW BG Alert is different than the Low Glucose Alert that applies only to CGM readings. Refer to <i>Chapter 2 in Section II</i> , pages 87-94 for information on CGM-related alerts.	

Alert
LOW BG Treat low BG. No bolus recommended. Monitor BG.
Confirm 

Alert: High BG 	
Cause	BG entry above 13.9 mmol/L.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press  to confirm.
Beeps/Vib	User selected, one time. No progression.
NOTE: The HIGH BG alert is different than the High Glucose alert that applies only to CGM readings. Refer to <i>Chapter 2 in Section II</i> , pages 87-94 for information on CGM-related alerts.	

Alert
HIGH BG Treat high BG. Check site. Check ketones. Monitor BG.
Confirm 

Alerts, Warnings and Alarms

Alert: Clear Program Basal Segments 🎵	
Cause	Clear command selected from BASAL OPTIONS screen.
Effect	Requires user confirmation to continue.
Message	Displayed until one of the two options is selected or until pump goes to sleep.
Action	Select “Clear Program” or “Basal Options”.
Beeps/Vib	User selected, one time. No progression.

Alert
Clear Program deletes all basal segments in this program.
Clear Program Basal Options

Alert: Basal Program Display Change 🎵	
Cause	Changing display of basal programs from 4 to 1 but program 1 is not currently active.
Effect	Requires user confirmation to continue.
Message	Displayed until confirmed or until pump goes to sleep.
Action	Press OK to confirm.
Beeps/Vib	User selected, one time. No progression.

Alert
1-weekday must be the active program to change the basal display setting.
Confirm

Warning: Basal Delivery Suspended 🎵	
Cause	Basal Edit was not saved.
Effect	Basal delivery stopped.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to select “Edit Basal”. Review basal edits and select “Save/Review”.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Basal edit not saved. Basal delivery suspended.
Edit Basal

Alerts, Warnings and Alarms

Warning: Suspend 	
Cause	Pump suspended manually.
Effect	All insulin deliveries stop.
Message	Displayed each time pump is awakened until confirmed and once every 15 minutes until action is taken.
Action	Press  to confirm. Resume delivery.
Beeps/Vib	User selected, once every 15 minutes No progression if confirmed each time displayed. Sweep/vib within one hour if not confirmed.

Warning
No delivery.
Pump is suspended.
Confirm

Warning: No Cartridge Detected, Deliveries Disabled 	
Cause	No cartridge detected after “Load cartridge” step during Prime/Rewind.
Effect	No insulin deliveries.
Message	Displayed when manually awakened until confirmed.
Action	Press  to confirm. Be sure Prime/Rewind sequence is completed with cartridge properly in place.
Beeps/Vib	User selected, once every 3 minutes. No progression if confirmed each time displayed. Sweep/vib within one hour if not confirmed.

Warning
No cartridge detected.
Delivery disabled.
Confirm

Alerts, Warnings and Alarms

Warning: Low Battery 🎵	
Cause	Battery life will last a minimum of 30 minutes.
Effect	Insulin deliveries continue.
Message	Displays when pump is awake until confirmed. Displays when triggered by event (such as bolus) & when manually awakened.
Action	Press OK to confirm. Insert new Battery.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Low battery.
Confirm

Warning: Low Cartridge 🎵	
Cause	Low insulin level reached.
Effect	Insulin deliveries may continue until Empty Cartridge alarm is triggered.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Replace with filled cartridge.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Low cartridge. XX U or less left.
Confirm

Warning: Exceeds Max Bolus 🎵	
Cause	Audio bolus delivery exceeds user-set maximum.
Effect	Bolus delivery stops.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram max bolus amount in the Setup Advanced menu.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Exceeds max bolus XX.XX U. No audio or combo bolus delivery.
Confirm

Alerts, Warnings and Alarms

Warning: Exceeds Max TDD 🎵	
Cause	Bolus delivery exceeds user-set maximum Total Daily Dose (TDD).
Effect	All insulin deliveries stop. Any Combo Bolus or Temp Basal is canceled.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram max TDD amount in the Setup Advanced menu. If the Warning is not confirmed by the time your pump clock passes midnight, the message will continue to be displayed.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Exceeds max TDD XXX U. No delivery. All bolus & active temp basal cancelled.
Confirm

Warning: Exceeds Max 2-hour Delivery 🎵	
Cause	Combined basal and bolus delivery exceeds user-set 2-hour maximum.
Effect	Insulin delivery stops. Any Combo Bolus or Temp Basal is canceled.
Message	Displayed when manually awakened until confirmed.
Action	Press OK to confirm. Reprogram Max 2-Hr amount in the Setup Advanced menu.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Exceeds max 2 Hr XXX U. No delivery. All bolus & active temp basal cancelled.
Confirm

NOTE: If the Exceeds Max TDD or the Exceeds Max 2-hour Delivery warning appears and is not confirmed, the warning will re-appear every 3 minutes. Basal deliveries will stop until either the warning is confirmed or that time period is complete. For the Exceeds Max TDD warning, Basal deliveries will resume the following day (beginning at midnight). For the Exceeds Max 2-hour Delivery warning, Basal deliveries will resume the next 2-hour time period.

Alerts, Warnings and Alarms

Warning: Exceeds Max Basal 🎵	
Cause	Basal delivery rate (or Temp Basal delivery) exceeds user-set maximum.
Effect	Basal delivery stops.
Message	Displayed when awakened (by basal delivery attempt every 3 minutes or manually) until confirmed.
Action	Press OK to confirm. Reprogram Max Basal amount in the Setup Advanced menu (or reprogram Temp Basal).
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Exceeds max basal XXX U/Hr. No basal delivery.
Confirm

Warning: Delivery Canceled due to Low Cartridge 🎵	
Cause	Basal or Bolus delivery exceeds insulin remaining in cartridge.
Effect	Basal or Bolus delivery stopped.
Message	Once per occurrence and each time awakened until confirmed.
Action	Press OK to confirm. Replace with full cartridge.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Delivery canceled due to low cartridge.
Confirm

Warning: No Prime, No Delivery 🎵	
Cause	Pump is not primed.
Effect	All insulin deliveries stop.
Message	Every 3 minutes or when awakened manually.
Action	Press OK to confirm. Disconnect, reprime.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Pump is not primed. No delivery.
Confirm

Alerts, Warnings and Alarms

Warning: Bolus Delivery Canceled 🎵	
Cause	User pressed function button on pump during bolus delivery.
Effect	Bolus delivery stopped.
Message	Every 3 minutes or when awakened manually.
Action	Press OK to confirm. If button was pressed accidentally, repeat steps to deliver remaining insulin units.
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour.

Warning
Bolus delivery canceled by user button press.
Delivered: X.XX U of X.XX U
Confirm

Alarm: Occlusion 🎵	
Cause	Occlusion detected.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Disconnect and prime to clear occlusion. Option to select Suspend (see Suspend Warning screen, page 77).
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see No Prime Warning screen, page 80.)

ALARM
OCCCLUSION DETECTED
No delivery.
Suspend
Confirm

Alerts, Warnings and Alarms

Alarm: Empty Cartridge 	
Cause	Cartridge empty.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Replace with full cartridge. Option to select “Suspend” (see Suspend Warning screen, page 77.)
Beeps/Vib	User selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see No Prime Warning screen, page 80.)

ALARM
EMPTY CARTRIDGE No delivery. Replace cartridge.
Suspend Confirm

Alarm: Replace Battery	
Cause	Battery life has a minimum of 3 minutes remaining.
Effect	All insulin deliveries stop.
Message	Continuous until battery is removed or has no power remaining.
Action	Remove battery to silence alarm. Insert new battery.
Beeps/Vib	MAX volume every 3 minutes until action taken. If not confirmed, will progress to 4 long tones.

ALARM
REPLACE BATTERY No delivery.
Remove battery to silence the alarm.

Alerts, Warnings and Alarms

Alarm: Call Service	
Cause	Hardware or software problem detected.
Effect	All insulin deliveries stop.
Message	Continuous until battery is removed.
Action	Press OK to silence alarm for 30 minutes (alarm can only be silenced once). Call Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
Beeps/Vib	User-selected, every 3 minutes. If not confirmed, progresses to sweep/vib within one hour.
NOTE: Some Call Service Alarms have a unique sound/vibration sequence and cannot be silenced by pressing OK. For these Alarms the usual progression is replaced by 3 chirps/vib repeated every 9 minutes for the first half hour. This is followed by 4 long tones/vib after that.	

ALARM
CALL SERVICE
No delivery. 52-00000001
Remove battery to silence the alarm.

Alarm: Auto-Off 	
Cause	Suspended due to no key press in user-set time period.
Effect	All insulin deliveries stop.
Message	Continuous until confirmed.
Action	Press OK to confirm. Adjust time period in the Setup Advanced menu.
Beeps/Vib	User-selected, every 3 minutes until confirmed. If not confirmed, progresses to sweep/vib within one hour. (Once confirmed, No Prime warning triggered, see No Prime Warning screen, page 80.)

ALARM
AUTO-OFF
No delivery.
No button presses in last XX hours.
Confirm

Continuous Glucose Monitoring (CGM)



CHAPTER 1 - CGM OVERVIEW

Section II of this Owner's Booklet covers instructions for using the Dexcom® continuous glucose monitoring (CGM) components in conjunction with your Animas® Vibe™ Insulin Pump. The Dexcom® CGM is an optional system (including a Sensor and Transmitter) that can be added to your Animas® Vibe™ Insulin Pump to provide continuous glucose monitoring (CGM) reporting on your pump. The Dexcom® CGM is packaged and available separately.

In addition to providing continuous insulin delivery, your Animas® Vibe™ System is designed to perform continuous glucose monitoring when used in conjunction with the Dexcom® CGM. Once you have completed training on your Animas® Vibe™ Insulin Pump and the Dexcom® CGM, and have activated the RF communication link between them, your Animas® Vibe™ System can provide an integrated approach to managing your glucose levels.

The Dexcom® CGM consists of a Dexcom G4™ Sensor (Dexsensor™) and Dexcom G4™ Transmitter (Dexmitter™). The Sensor is a disposable unit that you insert into your abdomen (belly) to continuously monitor your glucose levels for up to 7 days. The Transmitter is a reusable device that snaps into your Sensor Pod.

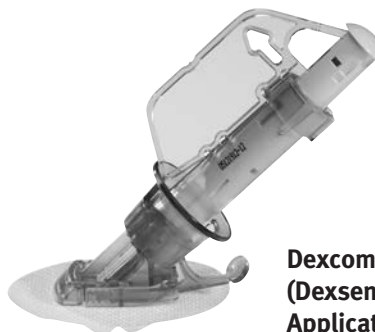
Together, the Sensor and Transmitter wirelessly send CGM readings every 5 minutes to your Animas® Vibe™ Insulin Pump where the data can be viewed and analyzed on the pump's color display. You can also set your pump to alert you when your CGM readings are too high or too low, or are rising or falling too quickly. Certain historical CGM data records are also available for review on your pump (see *Chapter 7 in Section II*, pages 119-122 for more information). You can use the Diasend® Web-based Diabetes Management System to track, review and analyze pump CGM data on your computer. Visit www.diasend.com/animas for more information.

You will need to calibrate the CGM on a regular basis with fingerstick values from a BG meter. Any commercially-available BG meter can be used for obtaining fingerstick calibration values.

CGM



**Dexcom G4™ Transmitter
(Dexmitter™)**



**Dexcom G4™ Sensor
(Dexsensor™) and
Applicator**

CHAPTER 2 - CGM SETTINGS

Setting your CGM Transmitter ID

Your CGM and pump communicate using RF communication. RF communication will be activated when you enter the unique CGM Transmitter ID/Serial Number into the pump and start your CGM session. This will ensure that communication takes place only between this pump and this CGM Transmitter. Any time you replace the Transmitter, you will need to enter the new Transmitter ID/Serial Number into the pump. Similarly, if your pump is replaced, you will need to enter the ID or S/N into the new pump.

NOTE: CGM menu options are not available while pump is suspended.

1. For the initial setup, remove the CGM Transmitter from the tray and wait 10 minutes for the CGM Transmitter to be activated and ready for use.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

2. From the MAIN MENU screen, scroll to “CGM” and press **OK**.

CGM Menu	
BG Cal.	
Trend Graph	
Start/Stop	
History	
Setup	
Main Menu	

3. Scroll to “Setup” on the CGM Menu screen press **OK**.

CGM Setup	
Sounds	
High Alert	
Low Alert	
Rise Rate	
Fall Rate	
Out of Range	
Transmitter	
CGM Menu	

Transmitter	
S/N	# 0 0 0 0 0
CGM Setup	

4. Scroll to “Transmitter” and press **OK**.
The CGM Transmitter screen will be displayed and “CGM Setup” will be highlighted.

Transmitter	
S/N	# 6 0 0 0 0
CGM Setup	

5. Scroll to the “S/N#” field. The last digit will be highlighted. Scroll to the first digit and then press **OK** so that the first digit is flashing.

NOTE:

- The ID/Serial Number appears on the underside of the Transmitter.
- The serial number should begin with 6 or 7.

Transmitter	
S/N	# 6 0 0 0 0
CGM Setup	

6. Use the **▲/▼** buttons to enter the first number/letter of the CGM Transmitter ID/Serial Number (found on the underside of the Transmitter). Press **OK** to move to the next digit and press **OK** again so that the second digit is flashing.

Transmitter	
S/N	# 6 8 7 A B
CGM Setup	

7. Repeat these steps until you have correctly entered all 5 numbers/letters from your CGM Transmitter ID/Serial Number. Press **OK** when the last digit is highlighted.

Transmitter	
S/N	# 6 8 7 A B
CGM Setup	

8. “CGM Setup” will be highlighted. If you need to edit the ID/Serial Number you just entered, scroll to the ID/Serial Number and re-enter the correct ID/Serial Number. With “CGM Setup” highlighted, press **OK** to return to the CGM Setup screen.

NOTE: If this is the first time you are entering an ID/Serial Number, all zeros (00000) will appear in the “S/N#” field.

Setting CGM Alerts on your Pump

You can set your pump to display and sound (beep/vibrate) an alert when:

- Your CGM readings are outside your target range.
- Your CGM readings may be rising or falling too quickly.
- Your CGM Transmitter is not within RF range of your pump.
- There are other CGM problems that require your attention.

On a few CGM settings, you can also select a “snooze time.” The snooze time tells your pump to display/sound the alert again at a set amount of time after first confirming the alert, if the condition causing the original alert has not been resolved. Consult with your health care team on the settings that are most appropriate for you.

CGM settings affect how and when your pump displays/sounds an alert, and how information is displayed on the CGM Data and CGM Trend screens.

You can set pump sounds for:

- High Alert
- Low Alert
- Rise Rate
- Fall Rate
- (Transmitter) Out of Range
- Other (alerts)

Pump sounds may be set to:

- Vibrate (Vib) only
- Low Volume (L) beep and vibrate
- Medium Volume (M) beep and vibrate
- High Volume (H) beep and vibrate (default setting)

NOTE: Your pump does not have the same “progressive” warnings and alarms safety system for CGM functions as it does for insulin delivery functions.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU screen, scroll to “CGM” and press **OK**.

CGM Menu	
BG Cal.	
Trend Graph	
Start/Stop	
History	
Setup	
Main Menu	

2. Scroll to “Setup” and press **OK**.

CGM Setup	
Sounds	
High Alert	
Low Alert	
Rise Rate	
Fall Rate	
Out of Range	
Transmitter	
CGM Menu	

3. Scroll to “Sounds” on the CGM Setup screen and press **OK**.

CGM Warning Sounds	
High Alert	H
Low Alert	H
Rise Rate	H
Fall Rate	H
Range	H
Other	H
CGM Setup	

4. The “High Alert” field will be highlighted on the CGM Warning Sounds screen. Press **OK** so that the highlight is flashing. Use the **▲** and **▼** buttons to select the desired sound for this alert. Press **OK**.

5. Repeat step 4 for the remaining alerts (Low Alert, Rise Rate, Fall Rate, Out of Range, Other).

6. When you are finished, scroll to “CGM Setup” and press **OK** to return to the CGM Setup screen.

Setting CGM Alert Values/Limits

You can enable/disable alerts and set CGM values/limits for:

- High Alert
- Low Alert
- Rise Rate
- Fall Rate

You can also set a “snooze time” for the High and Low Alert limits and the (Transmitter) Out of Range alert. See the pages that follow for more information on CGM Alerts.

NOTE:

- If you disable an Alert, it will not display/sound on the pump.
- You cannot disable the CGM Warning that displays/sounds when your most recent CGM reading is at or below 3.1 mmol/L.

High and Low Glucose Alerts

The High and Low (Glucose) Alerts will display/sound on your pump if the last CGM reading is at the limit or falls above or below these limits.

CGM Setup
Sounds
High Alert
Low Alert
Rise Rate
Fall Rate
Out of Range
Transmitter
CGM Menu

1. From the CGM Setup screen, scroll to “High Alert”. Press **OK**.

High Alert
Warn above
6.7 mmol/L
Snooze time
0 minutes
Enable
Yes
CGM Setup

2. With the “Warn above” field highlighted on the High Alert screen, press **OK** so that the highlight is flashing. Use the **▲/▼** buttons to select the desired level for the High Alert and press **OK**. You may set the High Alert from 6.7 mmol/L to 22.2 mmol/L (default is 11.1 mmol/L) in 1.1 mmol/L increments.

High Alert
Warn above
6.7 mmol/L
Snooze time
0 minutes
Enable
Yes
CGM Setup

3. The “Snooze Time” field will be highlighted. Use the **▲/▼** buttons to select the desired snooze time for the High Alert and press **OK**. The snooze time lets you set a time for the High Alert to display/sound again on your pump after you first confirm the alert, if the condition causing the original alert has not been resolved. You may set a snooze time from 0 to 300 minutes (default is 0 minutes – no re-alert) in 30 minute increments.

High Alert
Warn above
6.7 mmol/L
Snooze time
0 minutes
Enable
Yes
CGM Setup

4. Scroll to the “Enable” field and press **OK** to enter edit mode. The Enable setting gives you the option to display/sound the High Alert on your pump whenever the last CGM reading falls at or above this level. When you select “No”, this feature is disabled so that High Alerts will not display/sound on your pump. The default setting is “Yes” – enable.

5. When you are finished, scroll to “CGM Setup” and press **OK** to return to the CGM Setup screen.

Low Alert
Warn below 4.4 mmol/L
Snooze time 60 minutes
Enable Yes
CGM Setup

6. Scroll to “Low Alert” on the CGM Setup screen and repeat these steps for the Low (Glucose) Alert. You may set the Low Alert from 3.3 mmol/L to 5.5 mmol/L (default is 4.4 mmol/L) in 0.5 mmol/L increments, the snooze time from 0 to 300 minutes (default is 0 minutes – no re-alert) in 30 minute increments, and either enable or disable (default is “Yes” – enable) the Low Alert. When you are finished, scroll to “CGM Setup” and press **OK** to return to the CGM Setup screen.

NOTE: The High and Low (Glucose) Alerts that are set here will appear as horizontal lines on the graphs included in the CGM Trend screens. These levels will also affect the color coding of the Trend Arrows that appear in the CGM Data and CGM Trend screens. If you choose to disable these alerts, the horizontal lines will not appear on the Trend graph and the alerts will not display/sound on the pump. See *Chapter 6 in Section II*, pages 109-118 for more information on the CGM Data and CGM Trend screens.

Rise and Fall Rate Alerts

The Rise and Fall Rate Alerts will display/sound on your pump if your CGM readings begin to rise or fall at or faster than these limits.

CGM Setup
Sounds
High Alert
Low Alert
Rise Rate
Fall Rate
Out of Range
Transmitter
CGM Menu

1. From the CGM Setup screen scroll to “Rise Rate”. Press **OK**.

Rise Rate
Warn above 0.17 mmol/L/min
Enable Yes
CGM Setup

2. With the “Rise Rate” field highlighted on the Rise Rate screen, press **OK** to activate the edit mode (flashing highlight). Use the **▲/▼** buttons to select the desired value for the Rise Rate Alert and press **OK** to return to the CGM Setup screen. You may set the Rise Rate limit at either 0.11 mmol/L per minute or the default rate limit of 0.17 mmol/L per minute.

Fall Rate
Warn above 0.17 mmol/L/min
Enable Yes
CGM Setup

3. Scroll to “Fall Rate” on the CGM Setup screen and repeat these steps for the Fall Rate Alert. When you are finished, scroll to “CGM Setup” and press **OK** to return to the CGM Setup screen. You may set the Fall Rate limit at either 0.11 mmol/L per minute or the default rate limit of 0.17 mmol/L per minute.

NOTE: You can enable or disable (default is “Yes” – enable) the Rise and Fall Rate Alerts. If this feature is disabled, the Rise and Fall Rate Alerts will not display/sound on the pump.

(Transmitter) Out Of Range Alert

The (Transmitter) Out of Range Alert will display/sound on your pump if your CGM Transmitter is not within RF range of your pump (3.6 meters (12 feet)).

CGM Setup
Sounds
High Alert
Low Alert
Rise Rate
Fall Rate
Out of Range
Transmitter
CGM Menu

1. From the CGM Setup screen, scroll to “Out of Range”. Press **OK**.

Out of Range
Snooze Time
30 minutes
Enable
Yes
CGM Setup

2. With the “Snooze Time” field highlighted on the Out of Range screen, press **OK** to activate the edit mode (flashing highlight). Use the **▲/▼** buttons to select the desired snooze time for the alert and press **OK**. The snooze time lets you set a time for the Out of Range alert to display/sound again on your pump after you first confirm the alert, if the condition causing the original alert has not been resolved. You may set a snooze time from 21 to 201 minutes (default value is 30 minutes) in 3 minute increments.

3. When you are finished, scroll to “CGM Setup” and press **OK** to return to the CGM Setup screen.

NOTE: You can enable or disable (default is “Yes”– enable) the Out Of Range Alert. If this feature is disabled, the Out Of Range Alert will not display/sound on the pump.



CHAPTER 3 - INSERTING THE CGM SENSOR AND TRANSMITTER

To use the CGM in conjunction with your Animas® Vibe™ Insulin Pump, you will need a CGM Sensor and Transmitter. You will also need a BG meter and test strips for calibration and to make all treatment decisions. Once inserted and calibrated, the CGM Sensor will continuously measure and display your glucose readings for up to 7 days (166 hours after the 2-hour startup period). This chapter will show you how to insert the CGM Sensor and attach the CGM Transmitter.

CGM Sensor Overview

The CGM Sensor is a device that continuously measures your glucose levels. You will use a BG meter to calibrate your glucose readings measured by the CGM Sensor. The CGM Transmitter collects the CGM Sensor readings and sends them to the pump using wireless, radio frequency (RF) technology. This happens every 5 minutes for up to 7 days.

The CGM Sensor unit has an Applicator (Needle, Sensor, plastic housing), Sensor Probe, and Sensor Pod. The Applicator includes a Safety Lock/Transmitter Key to keep the Needle in place until you are ready to insert. After taking off the Safety Lock/Transmitter Key, you will insert the Sensor Probe just beneath the skin (subcutaneous tissue) of your belly using a small Needle inside the Applicator. The Needle is inserted just under the skin at an angle and carries the Sensor Probe with it. After inserting the Needle and Sensor Probe, pull the Needle back into the Applicator. Doing this leaves the Sensor Probe under your skin to continuously measure your glucose levels. The Applicator, with the Needle inside, is pulled off from the Sensor Pod and should be thrown away. Save the Safety Lock/Transmitter Key because you can use it to remove the CGM Transmitter at the end of a CGM session.

The Sensor Probe lies underneath your skin at an angle and continuously measures your glucose levels for up to 7 days. The Sensor Pod and CGM Transmitter (once snapped in) remain on your belly for the entire CGM Sensor wear period.

For information regarding possible CGM Sensor failures and errors, refer to *Chapter 10 in Section II*, pages 127-140.

⚠ WARNING: CGM Sensors may fracture on rare occasions. If a CGM Sensor breaks and no portion of it is visible above the skin, Do Not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the injection site. If you experience a broken CGM Sensor, report this to Customer Support or your local Animas distributor (see page 187).

CGM Transmitter Overview

The CGM Transmitter wirelessly sends your glucose information from the CGM Sensor to the pump. Once you insert the CGM Sensor, you will snap the CGM Transmitter into the Sensor Pod using the Transmitter Latch. The same CGM Transmitter is used when you change CGM Sensors.

As the CGM Transmitter nears the end of its 6 month warranty, it can sometimes lose communication with the pump. This can happen even if the pump and CGM Sensor/Transmitter are within 3.6 meters (12 feet) of each other. Once the CGM Transmitter battery has drained, you will need to replace the CGM Transmitter because it can no longer communicate (talk) to the pump. You can easily set up a new CGM Transmitter to talk with your pump (see *Chapter 2 in Section II*, pages 87-94).

NOTE:

- Your CGM Transmitter is re-used for many CGM Sensor uses.
- If you see **ANT** in place of a CGM reading this means your CGM Sensor/Transmitter and pump are not talking. This can happen even when your pump and CGM Sensor/Transmitter are within 3.6 meters (12 feet) of each other.
- The CGM Transmitter is designed and tested to withstand common electromagnetic interference, including airport security systems. To obtain information about bringing your CGM Transmitter through airport security check-in, contact the Federal Aviation Administration (or your country equivalent), or your local airport security office before traveling by air.
- Refer to *Chapter 3 in Section III*, pages 147-156 to troubleshoot CGM Sensor failures and errors.
- Refer to *Chapter 10 in Section II*, page 137 for information on the CGM Transmitter Low Battery Warning.

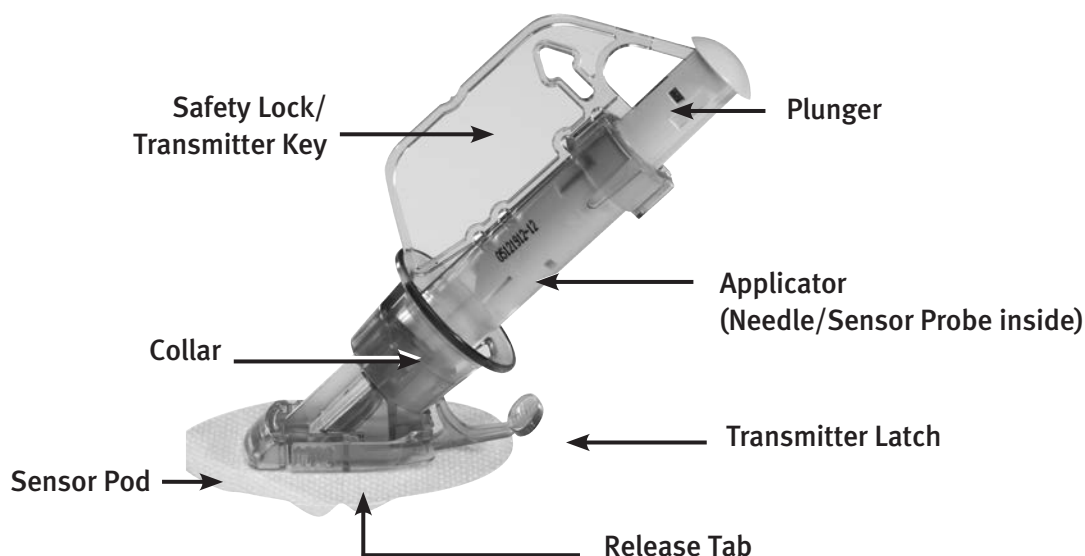
Before You Start

- Wash your hands thoroughly.
- Be sure your pump has sufficient battery life to avoid running out of battery power during use.
- Check that the date and time on your pump are correct.
- Make sure you have removed the CGM Transmitter from its tray and have waited 10 minutes for it to be activated and ready for use.
- If this is a new CGM Transmitter, make sure the correct Transmitter ID/Serial Number has been entered into your pump (see *Chapter 2 in Section II*, pages 87-94).
- Check the expiration date on the CGM Sensor before you start, to make sure you are not using an expired CGM Sensor. The expiration date format is YYYY-MM-DD.
- Quality check (“QC”) your BG meter per the manufacturer’s instructions to make sure it is providing you the best test results for calibration (e.g., check the code number and use the control solution if applicable to your BG meter).
- Clean the bottom of the CGM Transmitter with a damp cloth or alcohol wipe, and dry before you start a new CGM Sensor session.
- Make sure the date and time on your pump matches the date and time on your BG meter.

Inserting a new CGM Sensor and Transmitter

Review the CGM Sensor Applicator

Review the CGM Sensor Applicator picture below before using a new CGM Sensor.



NOTE: Always check the expiration date on the CGM Sensor packaging before opening the CGM Sensor for use. Never use expired CGM Sensors. The expiration date format is YYYY-MM-DD.

1. Remove the CGM Sensor from its packaging

⚠ PRECAUTION: The CGM Sensor is sterile in its unopened, undamaged package. Do Not use any CGM Sensor if its sterile package has been previously damaged or opened.

- Carefully remove the CGM Sensor from its packaging. Look closely at the CGM Sensor to make sure it is not damaged.
- The Applicator is a single use, disposable unit. The Safety Lock/Transmitter Key prevents you from accidentally releasing the Needle before you are ready.

2. Choose an insertion site

⚠ PRECAUTIONS:

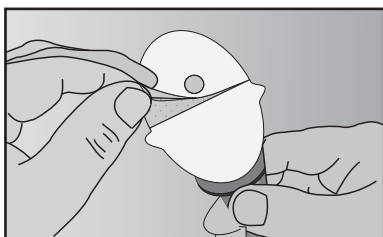
- Establish a rotation schedule for choosing each new CGM Sensor location. Avoid locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin or placing an insulin pump infusion set within 7.6 centimeters (3 inches) of a CGM Sensor.

Choose a site on a fatty area of your belly to place the CGM Sensor. You can choose a site above or below your belt line. The best areas to insert your CGM Sensor are usually flat, “pinchable,” and free from where rubbing can occur (i.e., pant line, seatbelts).

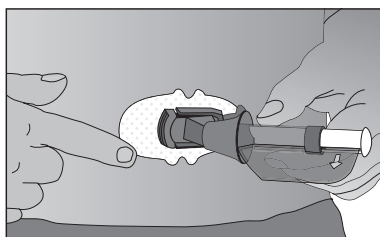
- Avoid areas with scarring, tattoos, or rough patches of skin from your insulin injections or pump.
- Avoid areas where you put pressure while sleeping.
- Choose an area at least 7.6 centimeters (3 inches) from where you plan to inject insulin or from where your pump infusion site is located.
- Avoid using the same spot repeatedly for CGM Sensor insertion. Never use the same site for two CGM Sensor uses in a row.
- You may need to shave the area where you plan to put the CGM Sensor so that the adhesive patch sticks well.
- Make sure there are no traces of lotions, perfumes or medications on the area. Clean the area first with an alcohol swab. Make sure the area is clean and completely dry before you insert the CGM Sensor.

3. Place the CGM Sensor

- After you have cleaned your skin, use the adhesive tape tabs to remove the adhesive backing from the Sensor Pod one half at a time. Hold the CGM Sensor by the plastic Applicator and try not to touch the sticky adhesive patch.
- Place the CGM Sensor on the chosen area of your belly. You can place the CGM Sensor flat, facing to the left or right of your belly button. Make sure the CGM Sensor is placed in the same direction shown in the picture below. You should not place the CGM Sensor pointing in the up or down direction.

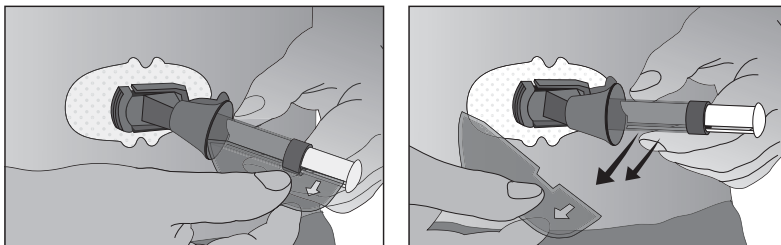


Remove the Adhesive backing



Adhere the CGM Sensor on the skin

- c. After placing the CGM Sensor, press firmly on and around the outside of the adhesive patch to make sure it is flat.
 - Pressing the patch to remove any wrinkles should help it stick better.
 - Press firmly over the entire patch area.
- d. Hold on to the Applicator. Then pull the Safety Lock/Transmitter Key straight out away from the Applicator, in the direction the arrow shows below.



Remove the Safety Lock/Transmitter Key

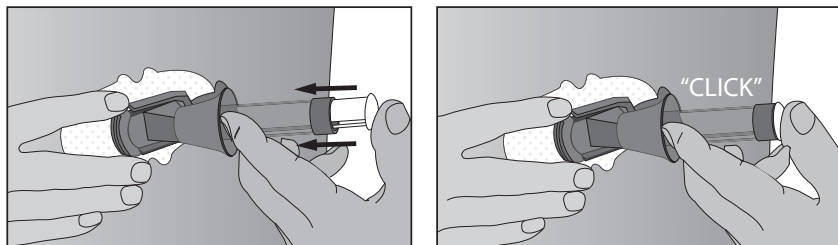
NOTE: The Safety Lock also serves as the Transmitter Key that is used later for CGM Transmitter removal. Keep this piece to help you remove the CGM Transmitter at the end of a CGM session. When your CGM session is over, follow the steps in *Chapter 9* in *Section II*, pages 125-126 to remove the CGM Transmitter.

4. Insert the CGM Sensor

Once you have placed the Applicator on your belly and removed the Safety Lock/Transmitter Key, you are ready to insert the CGM Sensor. Follow the next 4 steps (a–d) to successfully insert your CGM Sensor.

- a. Hold down the Sensor Pod with one hand or it may help to pinch up on your skin where the Sensor Pod is placed. With your other hand, place two fingers **above** the Collar on the barrel of the Applicator.
- b. Place your thumb on the Plunger. Push the Plunger down completely. This action inserts the Needle and Sensor Probe under your skin.

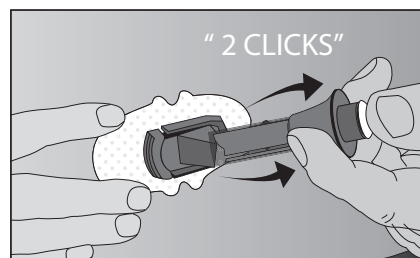
When you are pushing down on the Plunger, **Do Not** pull back on the Collar.



Push down the Plunger – Insert the Needle and Sensor Probe

- c. To remove the Needle, keep holding/pinching the Sensor Pod with one hand. With your other hand, place two fingers **under** the Collar. Then pull the Collar back towards your thumb. Stop when you hear 2 “clicks” or cannot pull back any more. This step pulls the Needle back into the Applicator and keeps the Sensor Probe under your skin

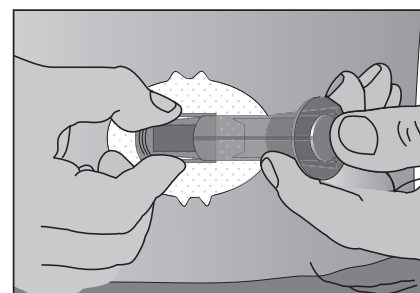
Remember to do this in the correct order: push Plunger down, then pull Collar up.



**Pull back the Collar –
Retract the Needle**

- d. Squeeze the ribbed Release Tabs on the sides of the Sensor Pod to remove the Applicator. When you squeeze the front Release Tabs, the back tabs will widen, allowing you to pull off the Applicator. After this step, only the Sensor Pod will be left on your body.

Make sure the Transmitter Latch is down (against your body) to remove the Applicator.



Release the Applicator

- e. The used Applicator can be thrown in the trash.

If you have any problems with insertion, save the CGM Sensor and Applicator and contact Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

5. Tape the Sensor Pod

The Sensor Pod should stay attached on its own. But, if the patch is peeling up, you can use medical tape (such as Blenderm™) for extra support. If you use tape, only tape over the white adhesive patch on all sides for even support. **Do Not** tape over the CGM Transmitter or any of the plastic parts of the Sensor Pod. **Do Not** tape under the Sensor Pod or leave any substance on the skin where you insert the Needle.

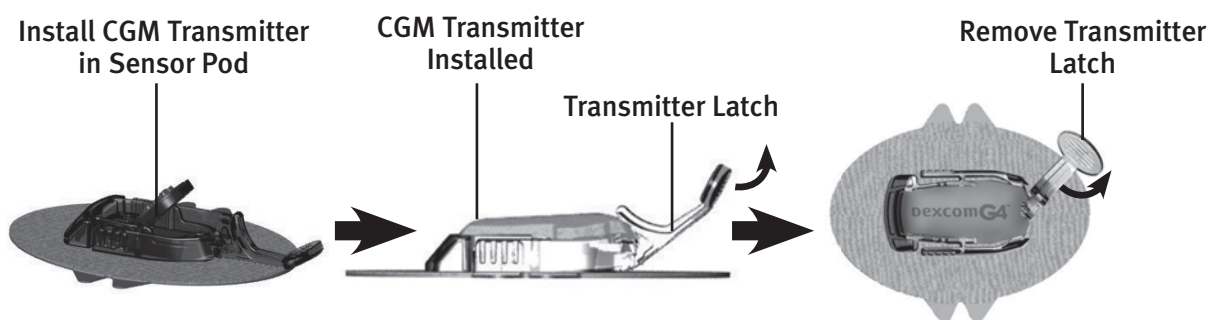


6. Attach the CGM Transmitter

The CGM Transmitter wirelessly sends your CGM Sensor glucose information to the pump. Once you have inserted your CGM Sensor, you will need to snap the CGM Transmitter into the Sensor Pod. Follow the steps below to attach your CGM Transmitter.

- a. Clean and dry the bottom of the CGM Transmitter with a damp cloth or an alcohol wipe before every use.
- Be careful not to touch the metal circles on the bottom of the CGM Transmitter.

- b. It may help to pinch up on your skin at the base of the Sensor Pod. Place the CGM Transmitter in the Sensor Pod with the flat side facing down.
- c. Pull the Transmitter Latch over the Transmitter to snap the CGM Transmitter into place. The CGM Transmitter should lie flat in the Sensor Pod. You should hear 2 “clicks.”
 - If you do not hear 2 clicks, the CGM Transmitter might not be fully snapped in.
- d. Make sure both sides of the CGM Transmitter are secure inside the Sensor Pod.
 - Do this by sliding your first and second fingers under the edge of the Sensor Pod (with your fingernails against your skin under the Transmitter Latch).
 - Place your thumb on top of the CGM Transmitter.
 - Then squeeze together to make sure the CGM Transmitter has been snapped in.



- e. Remove the Transmitter Latch by holding the end of the Latch and quickly twisting off the Latch away from your body. Remember to keep the Safety Lock/Transmitter Key.

NOTE:

- Make sure you hear 2 clicks when you snap the CGM Transmitter in place (see Step 6). This helps ensure your CGM Transmitter is water resistant. Your CGM Sensor (including the attached CGM Transmitter) is water resistant when showering, bathing, or swimming. The CGM Sensor/Transmitter has been tested to be water resistant when submerged for up to 2.4 meters (8 feet) for a maximum of 24 hours. For added protection you can use a shower cover.
- Make sure that you have the correct Transmitter ID/Serial Number entered into your pump. See *Chapter 2* in *Section II*, pages 87-94 for instructions on how to enter the Transmitter ID/Serial Number into your pump.
- Refer to *Chapter 3* in *Section III*, pages 147-156 for troubleshooting problems with CGM Sensor insertion.



Dexcom® CGM

CHAPTER 4 - STARTING A CGM SESSION

2-Hour CGM Startup Period

Once your CGM Sensor is inserted, and your CGM Transmitter ID/Serial Number is entered into your pump, you are ready to begin a CGM session. Each CGM session will last up to 7 days (166 hours after the 2-hour startup period), after which you will need to replace the CGM Sensor and start a new CGM session. During the 2-hour startup period, your CGM will make adjustments so that it adapts to your body's biological environment.

NOTE: Make sure you have removed the CGM Transmitter from its tray and have waited 10 minutes for it to be activated and ready for use.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU screen, scroll to "CGM" and press **OK**.

CGM Menu	
BG Cal.	
Trend Graph	
Start/Stop	
History	
Setup	
Main Menu	

2. Scroll to "Start/Stop" and press **OK**.

NOTE: If a session is currently active and "Start/Stop" is selected, you will go to the CGM Stop Session screen.

Start CGM	
Start CGM sensor session	
START	
CANCEL	

3. Scroll to "START" and press **OK** to begin the 2-hour startup period. Wait at least 8 seconds for the CGM session to start before pressing any other buttons on the pump. If you need to cancel the start of the CGM session, scroll to "CANCEL" and press **OK** to return to the CGM Menu screen.

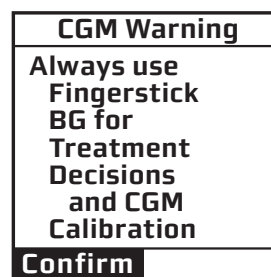
CGM Warning	
Invalid Transmitter ID	
Re-enter	
Cancel	

NOTE: If you entered an invalid Transmitter ID/Serial Number, you will be prompted to re-enter the correct Transmitter ID/Serial Number.

4. When you select “Start”, a CGM Warning screen will appear to remind you not to rely solely on CGM readings for making therapeutic adjustments.

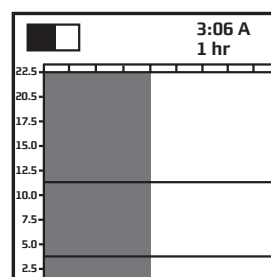
Always use Fingerstick BG for Treatment Decisions and CGM Calibration.

This Warning will appear every time you begin a new 2-hour CGM startup period. Press **OK** to confirm the Warning and continue with the 2-hour startup session. After pressing **OK**, you will go to the CGM Trend screen (see *Chapter 6* in *Section II*, pages 109-118).



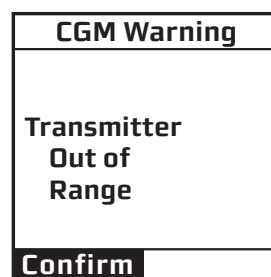
Once you start a CGM session, you can use the CGM Data and Trend screens on your pump to view the progress of the 2-hour startup period.

Keep your pump within 3.6 meters (12 feet) of your CGM Sensor/Transmitter during the 2-hour startup period for best communication. You can check that your devices are communicating by pressing the contrast button/CGM shortcut **ⓘ** on your pump while the pump is in sleep mode to display one of the CGM Information screens (see *Chapter 6* in *Section II*, pages 109-118). If a CGM Trend screen is displayed, a **shaded box** will appear on the top left of the screen to indicate the progress of the CGM startup period. The CGM session will start with the box completely shaded, but the shaded area will gradually diminish over the 2-hour startup period. The **shaded box** also appears on the CGM data screen.



Similarly, the graph area on CGM Trend screens will be shaded dark grey to start, but the grey area will gradually diminish over the 2-hour startup period. See *Chapter 6* in *Section II*, pages 109-118 for more information on the CGM Trend screen.

If the **ANT** symbol appears on the CGM Data or Trend screen and/or if your pump displays the Transmitter Out of Range Warning screen, then your devices are not communicating. Press **OK** to confirm the warning.



To troubleshoot CGM communication:

- Check that your pump and the CGM Sensor/Transmitter within 3.6 meters (12 feet) of each other. If not, move them closer. Wait about 5-10 minutes to see if the **shaded box** appears on the CGM Data or Trend screen (**ANT** will disappear).
- The pump and CGM Sensor/Transmitter may lose communication when they are near other metallic objects, or while you are lying on a waterbed or using an electric blanket.
- If the Warning screen appears again, verify that you have entered the correct CGM Transmitter ID/Serial Number into your pump.
- Refer to *Chapter 3* in *Section III*, pages 147-156 for troubleshooting problems with CGM communication.
- If the correct ID number has been entered, and the Warning screen continues to re-appear, contact Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

CHAPTER 5 - CGM CALIBRATION

In order for your CGM to work properly, you will be prompted to calibrate your CGM with fingerstick BG test results at various times during a CGM session. More specifically, you will need to be prepared to take a fingerstick test(s) with your commercially-available BG meter, and enter the BG results into your pump within 5 minutes of being prompted. The purpose of calibration is to correlate CGM Sensor readings to the reference BG meter to maintain CGM Sensor performance.

These are the required times for calibration:

- Startup Calibration – at the end of the 2-hour CGM startup period.
- Calibration Update – at least once every 12 hours during a CGM session.
- Recalibration – may be required if one of the fingerstick BG values entered for Startup Calibration or Calibration Update is not accepted by the pump.

⚠ WARNING: You should update the CGM's calibration every 12 hours at a minimum. The performance of the CGM when calibrated less frequently than every 12 hours has not been studied.

⚠ PRECAUTION: When entering fingerstick blood glucose values for CGM calibration, you must enter the exact blood glucose value that your blood glucose meter displays. Enter all fingerstick blood glucose values for CGM calibration within 5 minutes. Entering incorrect fingerstick blood glucose values, or fingerstick values that occurred more than 5 minutes ago, will affect CGM performance.

⚠ CONTRAINDICATION: Use of acetaminophen-containing medications while the CGM Sensor is inserted may affect the performance of the CGM.

When using your BG meter to obtain CGM calibration values:

- Always use a fingerstick test.
- **Do Not** use alternative sampling sites (e.g., palm or forearm).
- Always use the same BG meter for calibration for each CGM session.
- **Do Not** switch your BG meter in the middle of a CGM session.
- Follow your BG meter instructions for BG testing.
- It is important to follow proper BG testing techniques to ensure accurate calibration values and CGM performance.

2-Hour CGM Startup Period Calibration

CGM Warning
Enter 2 Startup BGs
Confirm

When the 2-hour CGM startup period ends, you will be prompted to enter 2 separate fingerstick BG values in your pump. Press **OK** to confirm the Warning.

CGM Menu
BG Cal. Trend Graph Start/Stop History Setup
Main Menu

1. Scroll to “BG Cal.” on the CGM Menu screen and press **OK**.

BG Calibrate
6.7 mmol/L
CALIBRATE CANCEL

2. The “BG value” field will be highlighted and flashing on the BG Calibrate screen. Use the **▲/▼** buttons to enter the first of 2 fingerstick BG values. Press **OK**. “CANCEL” will be highlighted. Scroll to “CALIBRATE” and press **OK**. If you need to cancel the BG value, scroll to “CANCEL” and press **OK**. In either case, you will return to the CGM Menu screen.

NOTE: The value on the BG Calibrate screen will start at 6.7 mmol/L the first time you calibrate, and at the current CGM reading when in calibration.

3. Repeat step 2 to enter the second BG value.

NOTE: Suspending insulin delivery during the 2-hour CGM Startup period will not affect the initial calibration sequence, and the CGM session will remain active.

12-hour CGM Calibration Update

Your CGM requires that you perform a calibration update at least once every 12 hours with a fingerstick BG value that you enter in the pump. Calibration update is necessary to make sure CGM Sensor readings remain accurate and are close to your BG meter readings. Follow the steps under the preceding section *2-Hour CGM Startup Period Calibration* for entering a BG value at any time. Any fingerstick BG value you may have entered in your pump during ezCarb and ezBG Bolus calculations may serve as a BG value for the calibration update (see *Chapter 10 in Section I*, pages 57-72). **You only need to enter 1 fingerstick BG value for each 12-hour CGM calibration update.**

If you forget to enter a BG value during each 12-hour period, you will be prompted to enter one. Press **OK** to confirm the Warning and follow the steps for entering a BG value. The CGM Warning screen will re-appear until you enter a new BG fingerstick value that is accepted for calibration.

CGM Warning
Enter BG
Confirm

CGM Recalibration

CGM Warning	
Enter BG	
Confirm	

When you enter a fingerstick BG value for calibration update, the CGM checks how well it is functioning compared to BG meter results. During each calibration update, you may be prompted for another fingerstick BG value. You may also be prompted for another fingerstick BG value during the 2-hour startup period.

When prompted, press **OK** to confirm the Warning and follow the steps for entering a BG value. You will continue to be reminded to enter a valid BG value until the BG value is accepted for recalibration. **BG** will appear on the CGM Data and CGM Trend screens in place of your current CGM reading until the BG value is accepted. You may also choose to end the CGM session (see *Chapter 8* in *Section II*, pages 123-124) after repeated unsuccessful attempts at recalibration.

NOTE:

- **Do Not** enter a BG value for CGM calibration if you see the **ANT** or **???** on the CGM Data or CGM Trend screens on your pump (see *Chapter 6* in *Section II*, pages 109-118). This means the pump and CGM Transmitter/Sensor are not communicating. Refer to *Chapter 3* in *Section III*, pages 147-156 for troubleshooting problems with CGM calibration.
- Any BG value you enter when using the ezBG or ezCarb feature on your pump can be used for CGM calibration update/recalibration. When prompted to choose if you want the BG value used for CGM calibration, select “Yes” and press **OK**.



CHAPTER 6 - VIEWING CGM INFORMATION ON YOUR PUMP

Your fingerstick BG meter only gives you a BG level at one point in time (like a still picture). However, the CGM information displayed on your pump will help you understand the rate of change and direction your glucose level is moving (like a video camera).

The CGM Sensor sits in the fluid under your skin, not in your blood. The CGM Sensor calculates a glucose reading from this fluid when you calibrate your CGM. So the glucose reading may be different than the fingerstick result you get from your BG meter.

During an active session, CGM readings will be sent from your CGM Transmitter to your pump every 5 minutes. You may use your pump to view and analyze CGM data using the CGM Data and CGM Trend screens. CGM readings between 2.2 and 22.2 mmol/L will display as the actual value on CGM Data and CGM Trend screens. CGM readings above 22.2 mmol/L will display as **HIGH**, and CGM readings below 2.2 mmol/L will display as **LOW**, on CGM Data and CGM Trend screens.

The screens provide important information about your current and previous CGM readings, whether your CGM readings fall above or below High and Low (Glucose) Alert levels, and whether your glucose levels may be rising or falling too fast. It is important that you focus on the CGM trends and rate of change on your pump, rather than a single CGM reading. See *Chapter 2 in Section II*, pages 87-94 for CGM settings that impact how information is displayed on the CGM Data and CGM Trend screens.

⚠ WARNING:

- **Treatment decisions should not be based solely on results from the CGM. You must confirm with a blood glucose meter before making therapeutic adjustments.**
- **You should update the CGM's calibration every 12 hours at a minimum. The performance of the CGM when calibrated less frequently than every 12 hours has not been studied.**

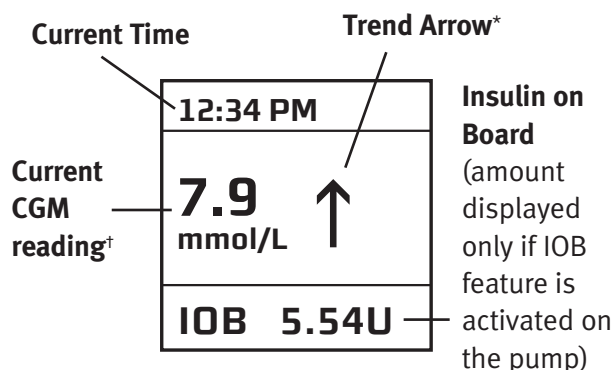
⚠ CAUTION: While insulin delivery is suspended, your CGM session will remain active, but CGM readings will not be recorded or displayed. As soon as insulin delivery resumes, CGM readings will start recording and displaying again.

CGM Data Screen

The CGM Data screen provides a snapshot of your current glucose status. Each CGM Data screen displays the current time on your pump, your current CGM reading, any Insulin on Board (IOB), and Trend Arrows that represent how fast your glucose levels may be rising or falling.

See the charts that follow on pages 111-112 for the meaning of the various symbols that might appear on the CGM Data screen.

Example CGM Data Screen

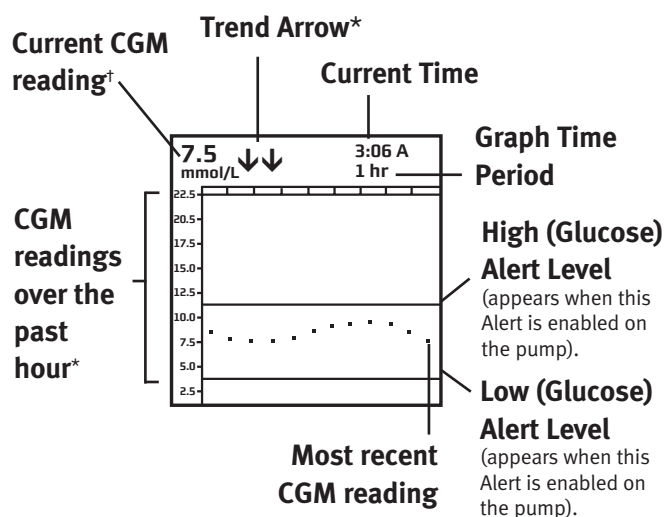


CGM Trend Screen

The CGM Trend screen provides a more detailed view of your glucose status, and includes a graphical display of your CGM readings over a time period you select (1, 3, 6, 12, or 24 hours). Each CGM Trend screen also includes the current time on your pump, your most recent CGM reading, High (Glucose) and Low (Glucose) Alert settings, and Trend Arrows that represent how fast your glucose levels may be rising or falling.

See the charts that follow on pages 111-112 for the meaning of the various symbols that might appear on the CGM Trend screen. During an active CGM session, you can access the CGM Trend screen by pressing the Contrast button/CGM shortcut  to wake up the pump.

Example CGM Trend Screen



When the pump is in sleep mode, pressing the Contrast button/CGM shortcut  will awaken the pump to the CGM Data or Trend screen last displayed when the pump went to sleep.

* Trend Arrows (on CGM Data and CGM Trend screens) and CGM data points (readings) on the CGM Trend screen are color coded. An explanation of the Trend Arrows and the color coding appears on the next page.

† A symbol may appear in place of your current CGM reading on CGM Data and CGM Trend screens. An explanation of these symbols appears on page 112.

CGM Data and CGM Trend Screen Arrows and Color Key

NOTE: The color key applies to the Trend Arrows on the CGM Data and CGM Trend screens, and CGM data points (readings) on the CGM Trend screens.

Trend Arrows

These arrows indicate whether your glucose is rising or falling and at what rate.

Symbol	Condition
↑↑	Rapidly rising: Your CGM glucose readings are rising more than 0.17 mmol/L each minute.
↑	Rising: Your CGM glucose readings are rising 0.11–0.17 mmol/L each minute.
↗	Slowly rising: Your CGM glucose readings are rising 0.06–0.11 mmol/L each minute.
→	Constant: Your CGM glucose readings are steady (not increasing/decreasing more than 0.06 mmol/L each minute).
↘	Slowly falling: Your CGM glucose readings are falling 0.06–0.11 mmol/L each minute.
↓	Falling: Your CGM glucose readings are falling 0.11–0.17 mmol/L each minute.
↓↓	Rapidly falling: Your CGM glucose readings are falling more than 0.17 mmol/L each minute.
No arrow(s)	No Rate of Change Information: The CGM cannot always calculate how fast your CGM glucose readings are rising or falling.

NOTE:

- Trend Arrows do not appear when CGM readings are “missing” on the CGM Data and CGM Trend screens (see *Missing CGM Readings*, pages 115-117 in this chapter).
- If the Trend Arrows are missing but you are concerned that your BG level may be rising or falling, take a fingerstick BG test to check your level. It is important to use the Trend Arrow information in conjunction with the CGM Trend screen graphs.
- **Do Not** take action based on the Trend Arrow information only: Use the information on the CGM Trend screen graph and results from your BG meter in addition to the Trend Arrows to make an informed decision about your glucose management.

Color Key
Red arrows (or red CGM data points on the CGM Trend screens) indicate your most recent CGM reading was at or above the High (Glucose) Alert level you set in your pump.
Green arrows (or green CGM data points on the CGM Trend screens) indicate your most recent CGM reading was between the High and Low (Glucose) Alert levels you set in your pump.
Blue arrows (or blue CGM data points on the CGM Trend screens) indicate your most recent CGM reading was at or below the Low (Glucose) Alert level you set in your pump.

Symbols That Might Appear in Place of your Current CGM Reading

These symbols may appear in place of your current CGM reading on the CGM Data and CGM Trend screens.

Symbol	Condition
	There is no active CGM session.
	A CGM Sensor was inserted within the last 30 minutes. No CGM readings are available.
	A CGM Sensor was inserted between 30 and 60 minutes ago. No CGM readings are available.
	A CGM Sensor was inserted between 60 and 90 minutes ago. No CGM readings are available.
	A CGM Sensor was inserted between 90 and 120 minutes ago. No CGM readings are available.
ERR 0	CGM Sensor Error 0. Wait 15 minutes and then enter at least one fingerstick BG value into the pump to recalibrate.
ERR 1	CGM Sensor Error 1. Wait 1 hour and then enter at least one fingerstick BG value into the pump to recalibrate.
BG	Fingerstick BG values needed for calibration.
???	The CGM reading cannot be displayed at this time.
ANT	There was no communication between the pump and CGM Transmitter within the last 5 minutes.
HIGH	Most recent CGM reading was higher than 22.2 mmol/L.
LOW	Most recent CGM reading was lower than 2.2 mmol/L.

Accessing the CGM Data and CGM Trend screens from the CGM Menu

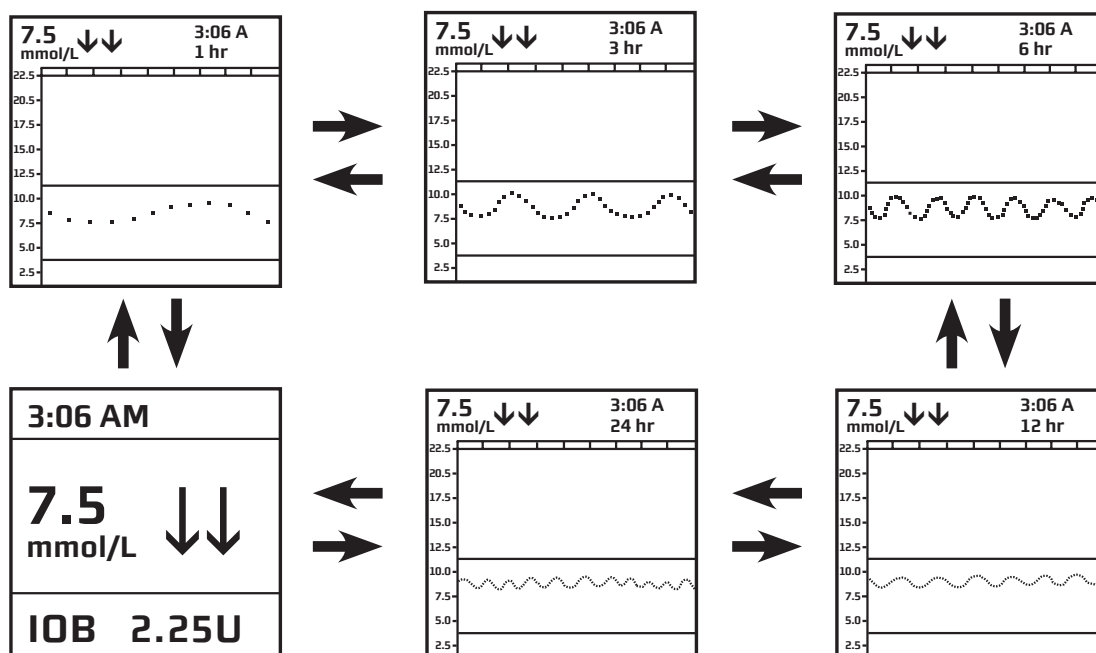
MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the MAIN MENU screen, scroll to “CGM” and press **OK**.

CGM MENU	
BG Cal.	
Trend Graph	
Start/Stop	
History	
Setup	
Main Menu	

2. Scroll to “Trend Graph” and press **OK**.

3. The last CGM Trend screen or Data screen (if you have just awakened the pump display) will be displayed. Use the **▲/▼** buttons to scroll through the 1-hr, 3-hr, 6-hr, 12-hr, and 24-hr CGM Trend screens, and then the CGM Data screen. CGM readings (data points) on CGM Trend screens track from right (most recent) to left (oldest) for the time period covered. The CGM Trend screens show you where your glucose levels have been and where your glucose levels are headed. To return to the CGM Menu screen, press **OK** while viewing the CGM Data screen or any CGM Trend screen.



CGM High/Low and Rise/Fall Rate Alerts

The High and Low (Glucose) Alerts let you know when your CGM readings fall outside the levels you set in the pump. The Rise and Fall Rate (of change) Alerts let you know when your CGM readings are rising or falling faster than the limits you set in the pump. You have the option to enable or disable these alerts, and customize the levels/limits based on your health care professional's recommendations (see *Chapter 2* in *Section II*, pages 87-94). In addition to the information on CGM Data and CGM Trend screens, these Alerts are another way of letting you know when your glucose levels may be getting dangerously high or low.

⚠ WARNING:

- The CGM is not designed to replace a blood glucose meter. The CGM must be used with a blood glucose meter.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the CGM results.

NOTE: The CGM Alerts discussed here are separate from the LOW BG and HIGH BG Alerts that display/sound on your pump when you enter a BG value below 3.9 mmol/L or above 13.9 mmol/L.

CGM Warning
Glucose Level is Above High User Limit
Confirm

High (Glucose) Alert

CGM Warning
Glucose Level is Below Low User Limit
Confirm

Low (Glucose) Alert

CGM Warning
Glucose Level is Falling Too Quickly
Confirm

Fall Rate
(of change) Alert

CGM Warning
Glucose Level is Rising Too Quickly
Confirm

Rise Rate
(of change) Alert

In these 4 instances, insulin deliveries and your CGM session will continue. Press **OK** to continue but be prepared to treat High or Low BG according to your health care professional's recommendations.

An additional CGM Alarm will display/sound on your pump when your most recent CGM reading is at or below 3.1 mmol/L. This Alarm limit is fixed, and cannot be changed or disabled. You will be re-alerted every 30 minutes if your current CGM reading remains at or below 3.1 mmol/L.

Refer to *Chapter 10* in *Section II*, pages 127-140 for additional information about CGM alerts that display/sound on your pump.

CGM Warning
Glucose Level is Below 3.1 mmol/L
Confirm

Missing CGM Readings

Periodically you may notice you are “missing” CGM readings on the CGM Data and CGM Trend screens. “Missing” means one or more CGM readings have not been received or were not understood by your pump, and are not available for display. You can identify “missing” data by a symbol appearing instead of your most recent CGM reading and trend arrow(s), or that there are gaps (no data) when displaying CGM Trend graphs.

This can happen when:

- Your pump and CGM Sensor/Transmitter are not communicating.
- Your pump does not recognize the CGM Sensor/Transmitter signal.
- Your pump is waiting for you to enter a fingerstick BG value to recalibrate the CGM.
- The CGM reading cannot be displayed.

WARNING:

- **The CGM is not designed to replace a blood glucose meter. The CGM must be used with a blood glucose meter.**
- **When CGM readings are missing, rely on results from your blood glucose meter. Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the CGM results.**

*Missing CGM Readings – **ANT** symbol appears in place of current CGM reading*

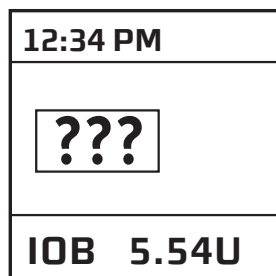
12:34 PM
ANT
IOB 5.54U

When the **ANT** symbol appears on either the CGM Data or CGM Trend screens, your pump did not receive the last CGM reading from your CGM Sensor/Transmitter. This is most likely due to your pump and CGM Sensor/Transmitter not being in RF range.

Try moving your pump and CGM Sensor/Transmitter closer to each other and wait at least 10 minutes for the next CGM reading to be received. Also verify that the correct CGM Transmitter ID/Serial Number has been entered into the pump. Your pump and CGM Sensor/Transmitter may lose communication when you are lying on a waterbed, using a electric blanket, or have other metallic objects nearby. If the **ANT** symbol remains on the display, there is still a problem with your pump receiving CGM readings. Call Customer Support or your local Animas distributor for assistance. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

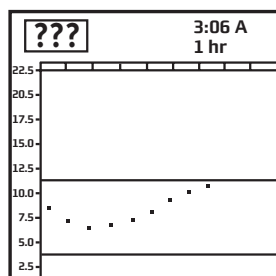
NOTE: When you see **ANT** instead of a CGM reading, taking additional fingerstick BG tests and entering the values into your pump will not result in further CGM readings appearing on the display. Any fingerstick BG values entered into your pump while the **ANT** is displayed will be ignored.

Missing CGM Readings – **???** appears in place of current CGM reading



Any time you see the **???** symbol on either the CGM Data or CGM Trend screens, your pump did not understand a CGM reading that it received from your CGM Sensor/Transmitter.

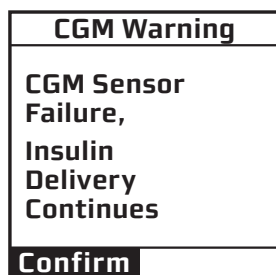
Check that your CGM Sensor is still sticking well to your skin and that nothing else is rubbing against the Sensor Pod, such as clothing or seat belts. Check that the CGM Transmitter is snapped in on both sides of the Sensor Pod.



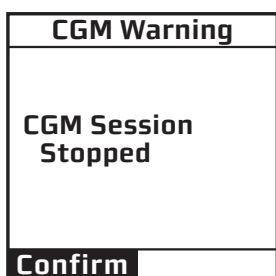
(Example CGM Trend screen with “missing” data)

NOTE:

- **???** may appear on CGM Data or CGM Trend screens for several hours. Call Customer Support or your local Animas distributor (see page 187) for assistance if **???** continues to appear for more than a few hours.
- When you see **???** instead of a CGM reading, taking additional fingerstick BG tests and entering the values into your pump will not result in further CGM readings appearing on the display. Any fingerstick BG values entered into your pump while the **???** is displayed will be ignored.



Sometimes the **???** problem will resolve itself and your CGM session will continue to provide CGM readings. Other problems may be serious enough to result in a CGM Sensor failure, and your CGM session will terminate. Your pump will notify you on the display if that happens. **Your pump will continue to deliver insulin if there is a CGM Sensor failure.** After pressing **OK** to confirm the Warning, call Customer Support or your local Animas distributor for assistance. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).



Missing CGM Readings – BG appears in place of current CGM reading

12:34 PM
BG
IOB 5.54U

Any time you see the **BG** symbol on either the CGM Data or CGM Trend screens, your pump requires that you enter a fingerstick BG value for a calibration update or recalibration.

CGM Warning
Enter BG
Confirm

A CGM Warning screen will also appear to remind you to enter a fingerstick BG value.

Follow the steps for entering a fingerstick BG value (see page 106). After entering a fingerstick BG value, a CGM reading should immediately appear on the display, and CGM readings should resume being updated every 10 minutes. If a CGM reading does not immediately appear, follow any display prompts and refer to *Chapter 10 in Section II*, pages 127-140 to troubleshoot any warnings, alarms, or alerts.

The **BG** symbol will remain on CGM Data and CGM Trend screens until the calibration update/recalibration was successful. Your pump will then begin/resume displaying CGM readings.



CHAPTER 7 - CGM HISTORY SCREENS

You can review certain historical CGM records on your pump, or you can use the Diasend® Web-based Diabetes Management System to track, review and analyze pump CGM history on your computer. Visit www.diasend.com/animas for more information.

CGM Session Start History

This selection displays the start date and time of your current CGM session.

NOTE: CGM Session Start history is only available if a CGM session is currently active.

MAIN MENU	
Bolus	
CGM	
Suspnd/Resum	
History	
Basal	
Setup	
Prime/Rewind	
Status	Home

1. From the Main Menu screen, scroll to “CGM” and press **OK**.

CGM MENU	
BG Cal.	
Trend Graph	
Start/Stop	
History	
Setup	
Main Menu	

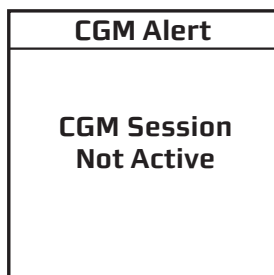
2. Scroll to “History” and press **OK**.

CGM History	
Session Start	
Last BG Cal.	
Warnings	
CGM Menu	

3. With “Session Start” highlighted on the CGM History screen, press **OK**.

CGM Session	
Record	1
17 Dec, 2010	
12:17PM	
Elapsed:	
0d, 4hr, 11m	
Remaining:	
6d, 19h, 49m	
CGM History	

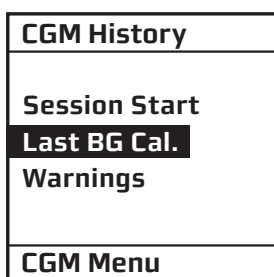
The start date and time of your current CGM session will appear on the display. Only your last (current) CGM Session Start record is available for viewing. To return to the CGM History screen, highlight “CGM History” on any Session Start record screen and press **OK**.



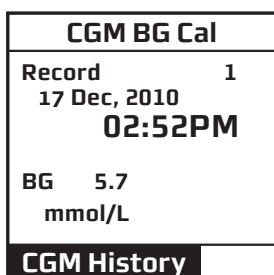
If there is no active CGM session, a CGM Warning screen will appear to remind you.

Last BG Calibration History

This selection displays the date, time and value of the last BG calibration entered in your pump.



1. From the CGM History screen, scroll to “Last BG Cal”. Press **OK**.



The BG value, date and time of your last BG calibration will appear on the display. Only your last (current) BG calibration record is available for viewing. To return to the CGM History screen, highlight “CGM History” on any BG Calibration record screen and press **OK**.

CGM Alert History

This selection displays the date, time, alert code and description of your last 300 CGM alerts.

CGM History
Session Start
Last BG Cal.
Warnings
CGM Menu

1. From the CGM History screen, scroll to “Warnings”. Press **OK**.

CGM Warnings
Record 1
17 Dec, 2010
12:17 PM
206-00000000
0000000000
Transmitter
Out of Range
CGM History

The CGM Warnings screen will be displayed, and “CGM History” will be highlighted. The most recent CGM Alert record will be displayed, along with the date, time, code, and description of the alert.

CGM Warnings
Record 1
17 Dec, 2010
12:17 PM
206-00000000
0000000000
Transmitter
Out of Range
CGM History

2. To go to other Alarm records, first scroll to the “Record” field at the top of the screen and press **OK** so that the highlight over the record number is flashing. Then use the **▲/▼** buttons to scroll to other CGM Alarm records.

To return to the CGM History screen, highlight “CGM History” on any Alert record screen and press **OK**.



CHAPTER 8 - COMPLETING A CGM SESSION

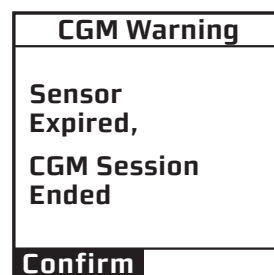
Each CGM session should last up to 7 days (168 hours including a 2-hour startup period), after which you will need to replace the CGM Sensor and start a new CGM session. You can also choose to end the CGM session early, or the CGM session might end earlier than the 7 days due to a CGM Sensor failure.

CGM Sensor Expiration

When you are within six hours of the expiration time, your pump will begin prompting you with a series of reminders that your session will be expiring shortly. You will be reminded with 6 hours remaining, 2 hours remaining, and 30 minutes remaining. Press **OK** to confirm the Warning at any of the reminder times.

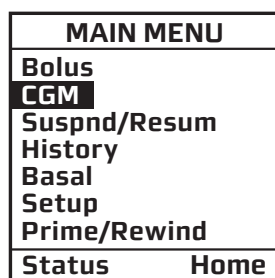


During this time your pump will continue to receive CGM readings. Once the final 30 minutes ends, you will be prompted that your CGM session has ended. Press **OK** to confirm the CGM Warning and return to the CGM Menu screen. You will no longer receive CGM readings on your pump until you replace the CGM Sensor and begin a new CGM session (see *Chapter 4* in *Section II*, pages 103-104).

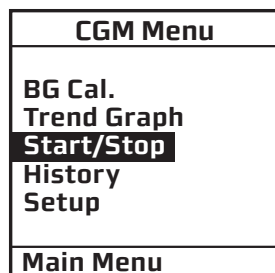


Ending a CGM Session Before the 7-Day Expiration Time

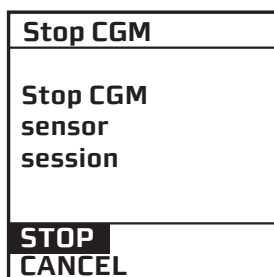
At any point during the CGM session, you may also choose to end the session before its intended expiration time.



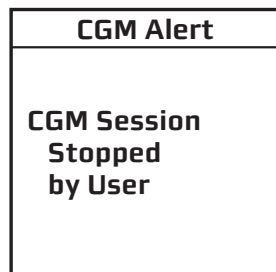
1. From the MAIN MENU screen, scroll to “CGM” and press **OK**.



2. Scroll to “Start/Stop” and press **OK**.



3. With “STOP” highlighted on the Stop CGM screen, press **OK**.



You will be notified on your pump display that you have stopped the CGM session. Press **OK** to confirm the Warning. After a few seconds, you will return to the CGM Menu screen.

Early CGM Sensor Expiration

In some cases, the CGM session may end before you have completed a full 7-day period. See *Chapter 10* in *Section II*, pages 127-140 for more information on the CGM Sensor Failure Warnings that may be displayed on your pump.

⚠ WARNING: CGM Sensors may fracture on rare occasions. If a CGM Sensor breaks and no portion of it is visible above the skin, Do Not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the injection site. If you experience a broken CGM Sensor, report this to Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

For patients undergoing an MRI with a retained wire broken off from a CGM Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

CHAPTER 9 - REMOVING THE CGM TRANSMITTER AND SENSOR

At the end of every CGM session, you will need to remove your CGM Transmitter and Sensor. First, gently peel up the adhesive patch from your skin to pull out your Sensor Probe (with the CGM Transmitter still in the Sensor Pod). Then remove the CGM Transmitter from the Sensor Pod and keep it for your next CGM session. The CGM Transmitter can be used for several CGM sessions up until the 6-month Transmitter warranty expires.

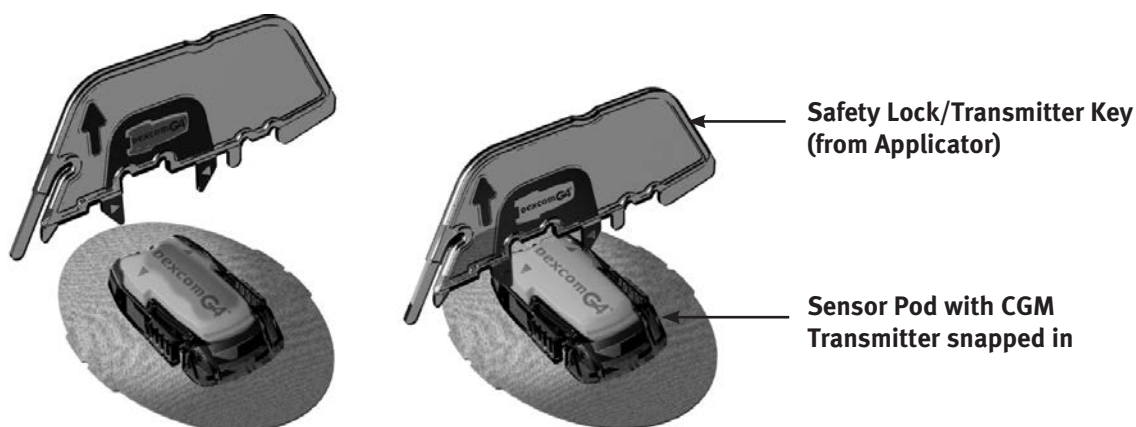
When it is time to replace your CGM Transmitter, follow proper instructions for disposal as the Transmitter contains a battery. See *Chapter 1* in *Section III*, pages 141-144 for information on disposal.

To remove the CGM Transmitter from the Sensor Pod, you can use either method below:

Method 1

The Safety Lock/Transmitter Key that was detached from the Applicator can be used as a tool to remove the CGM Transmitter.

1. Place the Sensor Pod on a table.
2. Hold the rounded edge of the Safety Lock/Transmitter Key.
3. Make sure the jagged edge of the Safety Lock/Transmitter Key is facing down (the direction away from the removal arrow) as shown below:



4. Insert the jagged edges so that they “hug” the CGM Transmitter wings in the Sensor Pod. Press the Safety Lock/Transmitter Key down until you cannot press down anymore, and the CGM Transmitter wings will “pop” out of the Sensor Pod.
5. Remove the CGM Transmitter and store it in a cool, dry place until your next CGM session.

Method 2

If you did not save the Safety Lock/Transmitter Key, you can simply use your pointer finger on each hand to spread out the tabs at the back of the Sensor Pod (end closest to the wings). The CGM Transmitter wings will “pop” out of the Sensor Pod.

NOTE:

- Remember to save your CGM Transmitter after each CGM Sensor removal. The same CGM Transmitter is used for each CGM session until you have reached the end of the CGM Transmitter battery life.
- The CGM Sensor can be thrown in the trash, but if you have problems with the CGM Sensor, save it and contact Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

CHAPTER 10 - CGM SAFETY SYSTEM AND ALERTS

Your pump **DOES NOT** have the same “progressive” warnings and alarms safety system for CGM functions as it does for insulin delivery functions. Refer to *Chapter 11 in Section I*, pages 73-84 for more information on the progressive warnings and alarms safety system for pump alarms not related to CGM functions.

This chapter reviews the warnings and alerts that appear and sound on your pump regarding CGM functions. See *Chapter 11 in Section I*, pages 73-84 for information on warnings, alarms, and alerts associated with insulin delivery on your pump.

If multiple CGM alerts, warnings, or alarms occur simultaneously, the pump will display the most critical one first. After confirming the condition with the highest priority (the one currently displayed), the alert, alarm, or warning with the next highest priority will be displayed until confirmed. Each alert, alarm, and/or warning must be confirmed separately until all simultaneous conditions have been confirmed.

The CGM warnings and alerts that are described in this chapter apply only to the CGM part of your Animas® Vibe™ System. They do not apply to any other CGM system.

Warning: 2 BG Values Required For 2-Hour Startup Calibration	
Cause	No BG values have been entered in the pump following the 2-hour CGM startup session.
Effect	Insulin deliveries continue. CGM does not start.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take 2 fingerstick BG tests and enter values in pump. Do Not enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. If confirmed, snooze for 15 minutes. No progression.

CGM Warning	
Enter 2 Startup BGs	
Confirm	

Warning: Second BG Value Required For 2-Hour Startup Calibration	
Cause	Only 1 of the 2 required BG values has been entered in the pump following the 2-hour CGM startup session.
Effect	Insulin deliveries continue. CGM does not start.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take fingerstick BG test and enter value in pump. Do Not enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. If confirmed, snooze for 15 minutes. No progression.

CGM Warning	
Enter 1 more of 2 Startup BGs	
Confirm	

Warning: BG Value Required For Calibration Update	
Cause	No BG values have been entered in the pump in the last 12 hours.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take fingerstick BG test and enter value in pump. Do Not enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	Silent (no Beeps/Vib). If confirmed, snooze for 15 minutes. No progression.

CGM Warning	
Enter BG	
Confirm	

Warning: BG Value Required For Recalibration	
Cause	The BG value entered has not been accepted for startup calibration or calibration update.
Effect	Insulin deliveries continue. CGM continues but with a possible CGM data gap.
Message	Displayed each time pump is awakened until confirmed, and action is taken.
Action	Press OK to confirm. Take another fingerstick BG test and enter value in pump. You will continue to be reminded to enter a valid BG value until the BG value is accepted for recalibration. Do Not enter a fingerstick BG value if ANT or ??? appear on the CGM Trend or Data screen.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning	
Enter BG	
Confirm	

Warning: Use Fingerstick BG For Treatment Decisions and CGM Calibration	
Cause	Appears at start of every CGM session.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Take fingerstick BG test before adjusting insulin dose, eating, exercising, or making any other therapeutic adjustments.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Warning	
Always use Fingerstick BG for Treatment Decisions and CGM Calibration	
Confirm	

Warning: CGM Session Expires In 6 Hours	
Cause	Current CGM Session has 6 hours left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 6 hours displayed when the Warning first appeared.
Action	Press OK to confirm. Replace CGM Sensor in 6 hours and start new CGM session.
Beeps/Vib	Silent (no Beeps/Vib), one time. No progression.

CGM Warning
CGM Session Expires In 06:00
Confirm

Warning: CGM Session Expires In 2 Hours	
Cause	Current CGM Session has 2 hours left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 2 hours displayed when the Warning first appeared.
Action	Press OK to confirm. Replace CGM Sensor in 2 hours and start new CGM session.
Beeps/Vib	Silent (no Beeps/Vib), one time. No progression.

CGM Warning
CGM Session Expires In 02:00
Confirm

Warning: CGM Session Expires In 30 Minutes	
Cause	Current CGM Session has 30 minutes left until 7-day period ends.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed. Each time the pump is awakened, the screen will display the actual time remaining rather than the original 30 minutes displayed when the Warning first appeared.
Action	Press OK to confirm. Replace CGM Sensor in 30 minutes and start new CGM session.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

CGM Warning
CGM Session Expires In 00:30
Confirm

Warning: CGM Session Expired	
Cause	Current CGM Session has expired.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Replace CGM Sensor and start new session.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

CGM Warning
Sensor Expired, CGM Session Ended
Confirm

Warning: Glucose Level Above High Glucose Alert Level	
Cause	Last CGM reading at or above limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.

CGM Warning	
Glucose Level is Above High User Limit	
Confirm	

Warning: Glucose Level Below Low Glucose Alert Level	
Cause	Last CGM reading at or below limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. If confirmed, snooze for user selected snooze time. No progression.

CGM Warning	
Glucose Level is Below Low User Limit	
Confirm	

Warning: Glucose Level Falling Faster Than Fall Rate Limit	
Cause	CGM readings are falling at or faster than Fall Rate limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

CGM Warning	
Glucose Level is Falling Too Quickly	
Confirm	

Warning: Glucose Level Rising Faster Than Rise Rate Limit	
Cause	CGM readings are rising at or faster than Rise Rate limit set in pump.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times, or until confirmed. No progression.

CGM Warning	
Glucose Level is Rising Too Quickly	
Confirm	

Warning: Invalid Transmitter ID	
Cause	Transmitter ID/Serial Number entered in pump is not valid.
Effect	Insulin deliveries continue. CGM does not start.
Message	Displayed until confirmed or until pump goes into sleep mode.
Action	Press OK to re-enter the correct ID or select “Cancel” and press OK to return to the CGM Menu. Refer to <i>Chapter 2 in Section II</i> , pages 87-94 for information on entering the ID number.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Warning
Invalid Transmitter ID
Re-enter Cancel

Warning: Pump and CGM Sensor/Transmitter Not Within RF range	
Cause	Pump and CGM Sensor/Transmitter are not within 3.6 meters (12 feet) of each other. Pump is unable to receive CGM readings and CGM Sensor/Transmitter is unable to receive BG values for calibration.
Effect	Insulin deliveries continue. CGM data gap for time period devices were not within RF range.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Move devices closer and wait 10 minutes.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. If confirmed, snooze for user selected snooze time. No progression.

CGM Warning
Transmitter Out of Range
Confirm

Warning: CGM Session Stopped	
Cause	CGM session stopped as a result of another Warning.
Effect	Insulin deliveries continue. CGM session stops.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Replace CGM Sensor and start new CGM session.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning	
CGM Session Stopped	
Confirm	

Warning: CGM Sensor Failure	
Cause	Sensor error indicating that Sensor is not functioning properly.
Effect	Insulin deliveries continue. CGM ends.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Call Customer Support or your local Animas distributor for assistance. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning	
CGM Sensor Failure, Insulin Delivery Continues	
Confirm	

Warning: CGM Sensor Error 0	
Cause	Sensor error indicating that Sensor is not functioning properly.
Effect	Insulin deliveries continue. CGM data gap during time periods Sensor was not functioning.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Wait 15 minutes and then enter at least one fingerstick BG value into the pump to recalibrate. If no CGM readings appear after entering additional BG values, Sensor should be replaced.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning	
CGM Sensor Error 0, Insulin Delivery Continues	
Confirm	

Warning: CGM Sensor Error 1	
Cause	Sensor error indicating that Sensor is not functioning properly.
Effect	Insulin deliveries continue. CGM data gap during time periods Sensor was not functioning.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Wait one hour and then enter at least one fingerstick BG value into the pump to recalibrate. If no CGM readings appear after entering additional BG values, Sensor should be replaced.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes up to 3 times or until confirmed. No progression.

CGM Warning	
CGM Sensor Error 1, Insulin Delivery Continues	
Confirm	

Warning: CGM Data Failure	
Cause	CGM and pump are having a communication problem.
Effect	Insulin deliveries continue. CGM session stops.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Call Customer Support or your local Animas distributor for assistance. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. No progression.

CGM Warning	
CGM Failure, Insulin Delivery Continues, Call Service XXX-XXXXXXX XXXXXXXXXX	
Confirm	

Warning: CGM Transmitter Low Battery	
Cause	CGM Transmitter battery power is low. Warning may also be caused by low temperatures.
Effect	Insulin deliveries continue. CGM continues but with possible data gaps.
Message	Displayed each time the pump is awakened until confirmed.
Action	Press OK to confirm. Try moving to a warmer area if you feel the temperature may be too low. Replace the CGM Transmitter if the Warning continues to appear.
Beeps/Vib	User selected (under CGM Setup menu options), every 3 minutes until confirmed. No progression.

CGM Warning	
Replace CGM Transmitter Low Battery	
Confirm	

Warning: Glucose Level Below 3.1 mmol/L	
Cause	Last CGM reading at or below 3.1 mmol/L (fixed limit set in pump – not user selected).
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed each time pump is awakened until confirmed.
Action	Press OK to confirm. Check BG with fingerstick test.
Beeps/Vib	Every 3 minutes until confirmed. If confirmed, snooze for 30 minutes. No progression.

CGM Warning
Glucose Level is Below 3.1 mmol/L
Confirm

Alert: CGM Session Stopped By User	
Cause	User stopped current CGM session.
Effect	Insulin deliveries continue. CGM session ends.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Alert
CGM Session Stopped by User



Alert: CGM Session Active	
Cause	Transmitter ID/Serial Number cannot be entered if CGM session is active.
Effect	Insulin deliveries continue. CGM continues.
Message	Displayed once for 4 seconds.
Action	None required.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Alert
CGM Session Active

Alert: CGM Session Not Active	
Cause	You are trying to enter a BG value into the pump but no CGM session is active.
Effect	Insulin deliveries continue. No CGM.
Message	Displayed once for 4 seconds.
Action	Start new CGM session if desired.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Alert
CGM Session Not Active

Alert: CGM Data Not Available While Pump Suspended	
Cause	CGM menu options not available on pump while it is suspended.
Effect	Insulin delivery currently suspended. Active CGM session continues but CGM data not available on pump. If you want to temporarily suspend insulin delivery but still view CGM readings, do not use the suspend delivery feature. Instead, you can program a temporary basal of 0 units for the time period you want basal delivery suspended, and still be able to view CGM readings.
Message	Displayed once for 4 seconds.
Action	Resume pump operation.
Beeps/Vib	User selected (under CGM Setup menu options), one time. No progression.

CGM Alert
Pump Suspended Must Resume pump to view CGM data

Section III

Care and Maintenance and Other Technical Information About Your Animas® Vibe™ System



CHAPTER 1 - CARE AND MAINTENANCE

Section III of this Owner's Booklet covers safety, maintenance, troubleshooting, lifestyle, and technical information about your Animas® Vibe™ System.

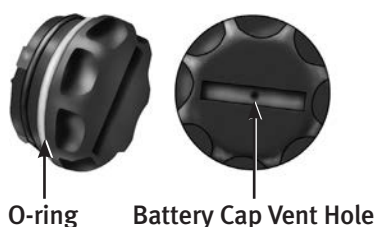
Care and Maintenance of your Animas® Vibe™ Insulin Pump

The Vents

Your pump features a redundant Vent Safety System. Vents serve two purposes. First, they allow air to enter and exit your pump so that pressure is equalized under a variety of environmental circumstances, such as changes in altitude. Second, the vents are backed by a special membrane, which keeps water from entering your pump.

Battery Cap with O-ring and Vent

Your battery cap contains an o-ring and vent. The vent is a tiny hole backed by a membrane, which allows air to pass through but prevents water from entering. The o-ring helps to keep your pump waterproof. It is recommended that you change the battery cap/vent every six months. If you work in a dusty environment such as a construction site, mill, cement factory, etc., or if you are a frequent swimmer, you should change your battery cap every 3 months. You can call Customer Support or your local Animas distributor (see page 187) to order an extra battery cap.



⚠ WARNING: Under no circumstances should you introduce any kind of sharp object into the vent openings to clean them. Doing so could compromise your pump's waterproof capabilities. If at any time you suspect the vent opening is clogged, replace the battery cap.

Cleaning

⚠ CAUTION: Do Not use household or industrial cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your pump. Never put your pump in the dishwasher or use very hot water to clean it. Use only a very mild detergent (for example a drop of liquid soap in a glass of water) and a lint-free cloth.

Never put your pump in a microwave oven or baking oven to dry it. Use a soft towel.

Never clean the battery or insulin cartridge compartments.

General Wear and Tear

If you drop your pump or it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and clear, that the cartridge cap, battery cap and infusion set are properly in place. Check for leaks around the cartridge by wrapping a piece of tissue around the connection area. Cracks, chips or damage to your pump may impact the battery contact and/or the waterproof feature of your pump. Call Customer Support or your local Animas distributor (see page 187) if you identify or suspect your pump is damaged. They will help determine if your pump should be replaced.

Disposal

International regulations require controlled disposal of devices such as insulin pumps. Contact Customer Support or your local Animas distributor (see page 187) for disposal instructions.

Dispose of batteries according to your local environmental regulations.

Care and Maintenance of your Dexcom® CGM

The CGM Transmitter and Sensor require minimal maintenance. Keep the following tips in mind:

CGM Sensor and Transmitter

- Insert the CGM Sensor only as directed.
- Snap the CGM Transmitter completely into the Sensor Pod in the correct alignment.
- Calibrate the CGM Sensor/Transmitter every 12 hours as directed.
- **Do Not** expose the CGM Sensor/Transmitter to water deeper than 2.4 meters (8 feet) and **Do Not** expose the CGM Sensor/Transmitter to water for over 24 hours.
- Remove the CGM Sensor/Transmitter as directed.
- Keep the CGM Transmitter clean and protected when not in use.

Accessories

- Maintain your fingerstick BG meter as directed by the manufacturer.
- Only use Dexcom®-supplied parts (CGM Sensors and Transmitters) with your Animas® Vibe™ System.
Do Not use Sensors and Transmitters from other companies.

Storage

CGM Sensor

- Keep the CGM Sensor in its sterile packaging until you are ready to use it.
- **Do Not** insert CGM Sensors past the expiration date printed on the CGM Sensor packaging.
- Store at room temperature for the length of its shelf life.

CGM Transmitter

- Keep the CGM Transmitter clean and protected when not in use.
- CGM Transmitter Warranty is 6 months.
- Storage Temperature should be 2°–45° C (36°–113° F).

Cleaning

Cleaning the CGM Transmitter:

1. Use an alcohol wipe or equivalent to clean the CGM Transmitter. Avoid wipes containing adhesive properties (e.g., Smith & Nephew IV Prep).
2. Place the CGM Transmitter on a clean, dry cloth and air dry for 2-3 minutes.

Disposal

The CGM Sensor may be discarded after removal. If you have any problems with the CGM Sensor, save it and contact Customer Support or your local Animas distributor (see page 187) before discarding.

International regulations require controlled disposal of devices such as Transmitters. Contact Customer Support or your local Animas distributor (see page 187) for disposal instructions.

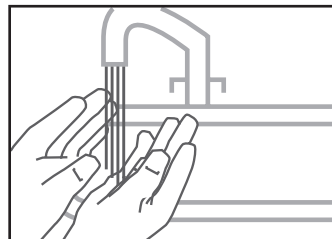
Your CGM transmitter contains a small battery. Dispose of batteries according to your local environmental regulations.

CHAPTER 2 - LENS PROTECTION FILM APPLICATION INSTRUCTIONS

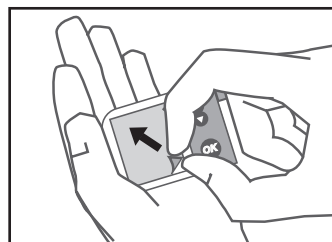
Your pump display Lens Protection Film Kit contains 3 lens protection films, the film application solution (901-002-01) and a rubber squeegee.

Follow the instructions below for proper application.

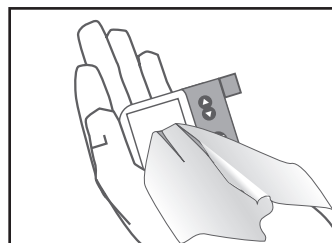
1. Wash your hands with mild soap and water.



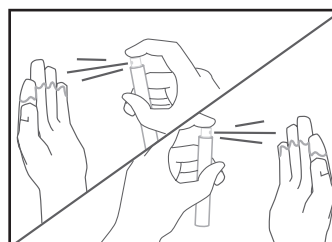
2. Slowly remove existing lens protection film.
 - **Do Not** use heat or metal instruments.



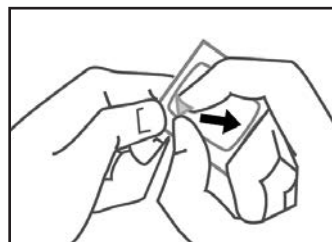
3. Clean lens with a dry lint free cloth.
 - Film can be applied without disconnecting pump.



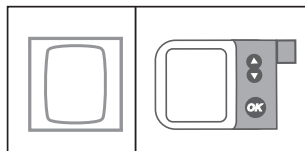
4. Spray fingers with film application solution, 901-002-01
 - Solution contains isopropyl alcohol.
 - Shake before use.
 - **Do Not** ingest.



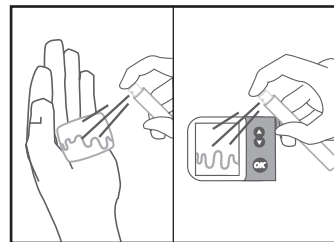
5. Remove lens film from paper backing.
 - Touch with wet fingers only.
 - Hold adhesive side up.
 - **Do Not** let film adhere to itself.



6. Spray entire film adhesive area and lens with solution.

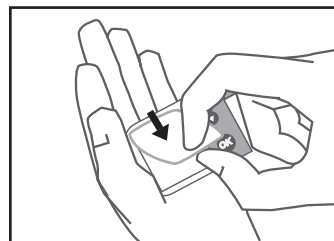


NOTE: Before proceeding, make sure the film orientation matches the frame orientation of the lens.



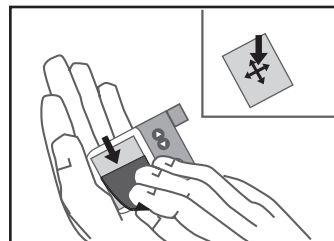
7. Place film onto lens.

- Place adhesive side down, facing lens.
- **Do Not** press into place.
- If needed, remove film, reapply solution, and reposition film to align all edges.



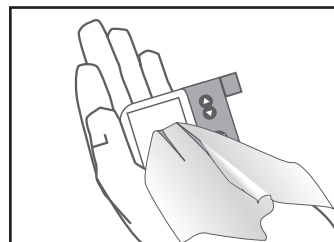
8. Pull squeegee firmly across film.

- Start from center of lens and pull in all directions, to remove moisture and bubbles from under the surface.
- Pull squeegee across all corners and edges to adhere film.



9. Remove excess moisture with lint free cloth.

- If necessary, apply direct pressure to film edges until film is adhered to lens.
- Your pump can be used immediately after film application.
- Wash hands thoroughly after film application.



IMPORTANT INFORMATION: The viewing area of the pump display should be visually clear after film application. If air or moisture bubbles are visible after the film is installed, peel the film up from one edge at least to the location of the bubbles. Re-spray the film adhesive and the pump surface with solution, and re-apply the film with the squeegee. If this does not remove the bubbles, reinstall a new film.

CHAPTER 3 - TROUBLESHOOTING GUIDELINES

It is a good idea to set up a troubleshooting procedure to use anytime you suspect something might be wrong. Work with your health care team to establish guidelines in the event of a problem.

Hypoglycæmia

⚠ WARNING: Low BG is a risk for anyone using insulin therapy. You may experience one or more of the following symptoms:

- Shakiness; rapid heart rate; nervousness; perspiration; cold, clammy skin; weakness; blurred or double vision; sudden hunger; tingling in your hands, lips, or tongue; headache and confusion.
- If you experience symptoms of hypoglycæmia, you should immediately eat a quick-acting carbohydrate (glucose tablets, juice, or hard candy).
- Do Not rely on CGM readings if you experience symptoms of hypoglycæmia. If you suspect hypoglycæmia, obtain a fingerstick value with your BG meter.
- If your BG is abnormally low, Do Not attempt to program your pump yourself. Get help.
- Treat hypoglycæmia immediately.

Rule of 15*

1. Consume 15 grams of quick-acting carbohydrate
2. Wait 15 minutes
3. Recheck BG with BG meter
4. If BG is < 3.9 mmol/L, repeat above

Troubleshooting hypoglycæmia:

INSULIN PUMP

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Basal rate programmed incorrectly	Check times and rates, remember to review basal programs when making any changes.
Clock time incorrect	Reset clock to current time, being careful to check AM & PM.
Pump exposed to MRI	Disconnect from pump. Call Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

* Walsh JR & Roberts R., Pumping Insulin. 2006. San Diego: Torrey Pine Press.

Troubleshooting hypoglycemia:

FOOD INTAKE

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Bolus too large	Check bolus amounts and times. Bolus only enough to lower your BG to normal level.
Low carbohydrate intake for bolus	Measure carbohydrates accurately. See dietitian for carb counting review. May need recalculation of I:C ratio; consult with health care team.
Improper timing of bolus	Match timing of bolus with intake of food. Check BG prior to meal bolus and adjust accordingly.
Alcohol consumption	May cause hypoglycemia (or may cause hyperglycemia). Eat food when drinking alcohol. Be cautious with bedtime bolus. Always check BG before going to bed. Check BG at 3 am. Consult health care team.

ACTIVITY

POSSIBLE CAUSE OF LOW BG	SUGGESTED SOLUTION
Did not Suspend pump or activate Temp Basal	Consult health care team for guidelines for use of Temp Basal rate during exercise.
Low carbohydrate intake prior to exercise	If not decreasing insulin prior to or during exercise, may need to eat foods containing carbohydrate prior to exercise.
Unplanned activity (shopping)	If BG is below 5.6 mmol/L, eat snack prior to exercise. Frequent BG testing before, during and after any activity.
Long or intensive exercise	Effects of exercise can be present for hours after activity has stopped. Consult with health care team for specific guidelines.
Insulin infusion site is too close to the CGM Sensor insertion site	Make sure the sites are at least 7.6 centimeters (3 inches) away from each other.

NOTE: Always check BG levels with a fingerstick test from your BG meter.

Preventing hypoglycæmia:

- Check BG a minimum of four times a day, and more frequently with exercise.
- If your CGM readings suggest possible hypoglycæmia or hyperglycæmia, check your BG frequently.
- Keep accurate track of carbohydrates in the foods you eat.
- Consult your health care professional if you are experiencing frequent hypoglycæmia or have a severe low that may require the help of another person.

It may be necessary to adjust your basal rates, bolus doses, or review your BG Target goals, along with your daily regimen of food and exercise. If you have a low BG level (hypoglycæmia), follow the routine established for you by your health care team.

- It is important to monitor your BG frequently, including periodic checks overnight.
- Investigate the cause of hypoglycæmia.

Hyperglycæmia

Because your pump uses only rapid-acting insulin, you will not have a reserve of long-acting insulin in your body. This means that any interruption in the delivery of insulin by your pump can quickly result in a sharp rise of your BG levels.

Hyperglycæmia (high BG) can occur within two to four hours after insulin delivery stops, and DKA (diabetic ketoacidosis) can develop within four to ten hours.

Several things can cause a high BG value. The most common problems and causes of high BG are listed in the following table, as are some suggested solutions.

DKA (Diabetic Ketoacidosis)

Hyperglycæmia can lead to DKA. If your BG is above 13.9 mmol/L, **check blood or urine ketones per your health care team. Remember, the first signs of DKA are often nausea and vomiting.** Also remember that because you no longer have long-acting insulin in your system, DKA can develop quickly if you ignore and/or fail to troubleshoot potential problems.

Troubleshooting hyperglycemia:

INFUSION SET

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Redness, irritation, inflammation, swelling, discharge or discomfort	Change infusion set tubing and site. Contact health care team.
Bump or nodule at infusion site	Change infusion set and rotate sites. Avoid this area for site selection.
Scar tissue	Avoid this area for site selection.
Catheter inserted in area of friction	Avoid waistline and friction areas.
Kink in tubing/catheter	Change infusion set tubing and site.
Infusion set not primed (air in tubing)	Disconnect tubing from body. Prime tubing completely.
Cannula not filled	Verify filling volume from manufacturer's instructions, and program that amount when prompted on the FILL CANULLA screen as needed.
Tubing not tightly attached to cartridge	Tighten tubing attachment to cartridge.

INSULIN

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Cloudy, clumpy, crystallized, or expired insulin, or insulin exposed to extreme temperatures	Remove infusion set and cartridge and discard. Use new vial of insulin.

FOOD INTAKE

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Bolus insufficient or omitted	Review carbohydrate counting and I:C ratio settings.
High protein or fat intake	Consult dietitian; may need to count protein and fat.
Long meal, continuous snacking, slowly-absorbed food (high fiber), delayed digestion (gastroparesis)	Consult health care team. May need to use extended bolus or combination bolus option.
Improper bolus timing	Consult health care team.

Troubleshooting hyperglycaemia:

ACTIVITY

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Less activity	Use Temp Basal increase. Consult health care team.
Overuse of Temp Basal reduction	Record amount of time for changes. Frequent BG testing to document changes.
BG higher than 13.9 mmol/L with ketones before exercise	BG will increase with exercise when ketones are present. Do Not exercise when ketones are present. Consult health care team for exercise guidelines.

⚠ CAUTION: Infusion set should be changed every 2 to 3 days or as recommended by your health care team.

Always use clean technique!

Notify health care team with signs or symptoms of infection at your insulin infusion site or CGM Sensor insertion site!

OTHER

POSSIBLE CAUSE OF HIGH BG	SUGGESTED SOLUTION
Medications (steroids, terbutaline, acetaminophen, other hormone treatments)	Inform health care team of all medication changes or additions.
Infection, illness, virus	Refer to Sick Day Management Guidelines.
Pre-menstrual cycle	Consult health care team. May need to use Temp Basal or set additional Basal Program.
Pregnancy	Insulin requirements may increase in later trimesters. Consult health care team.
Weight changes	May need recalculation of basal or bolus doses. Consult health care team.

⚠ WARNING: Consult your health care team before making any changes in your basal rates or bolus calculation settings.

**When in doubt, change it out! 1. Follow guidelines provided by your health care team.
2. Change infusion set. 3. Check for ketones. 4. Take rapid-acting insulin by injection.**

Problems with Infusion Sets, Sites and Cartridge

A number of problems can occur with infusion sets and sites, the most common of which are listed in the following table, along with some suggested solutions.

POSSIBLE PROBLEMS	SUGGESTED SOLUTION
Air bubbles in tubing	Always fill your pump cartridge with room temperature insulin. Check Luer lock connection and tubing; change infusion set if needed. If using a disconnect set, remove the set from your infusion site and prime the bubbles out. Check that cartridge plunger is straight and the cartridge is not filled with more than 2.0 mL of insulin.
Kinked tubing	Straighten tubing if needed; replace infusion set if needed.
Dislodged needle or cannula	Change infusion set and site. Consider using different tape, dressing or infusion set. A cannula cannot be pushed back into skin successfully.
Blood in tubing (insulin looks pink or red)	Change infusion set and site. Check needle/cannula angle at new infusion site.
Insulin leak	Check Luer lock connection by wrapping a tissue around it to check for moisture; tighten or change cartridge and infusion set if needed. Check that cartridge is not filled with more than 2.0 mL of insulin. Do Not tighten cartridge cap while the infusion set is connected to your body.
Redness, tenderness, lumps, itching, warmth, discharge	Change infusion set and site; use clean technique. Treat old site for infection if necessary. Consult health care team.
Cartridge Reused	Do Not reuse cartridge. Cartridge is for single use only.

Problems with CGM Sensor Insertion

Problems can occur during CGM Sensor insertion, and in keeping the Sensor Pod attached to your body. The most common problems are listed in the following table, along with some suggested solutions.

POSSIBLE PROBLEMS	SUGGESTED SOLUTION
Safety Lock/Transmitter Key will not detach from the Applicator	• Make sure to pull straight out using the arrows on the Safety Lock/Transmitter Key as a guide. • Do Not wiggle back and forth.
Applicator Collar will not pull up	• Make sure the Plunger is completely pressed down before pulling the Collar up. • When pulling the Collar up you should hear 2 clicks. • Try using more force when pulling the Collar up.
Applicator will not detach from the Sensor Pod	• Pull the Collar all the way up. It should be very close to the top of the Applicator. • Make sure the Transmitter Latch is down before squeezing the Release Tabs. • Then squeeze the center part of the ribbed Release Tabs on the side of the Sensor Pod, and lift the Applicator away from your body.
Transmitter Latch will not remove easily	• Hold the Sensor Pod down with one hand and twist the Latch with the other hand to remove it. • Do Not try to snap it straight off.
Sensor Pod does not remain stuck on body	• Do Not use any cream or lotion on your skin where you attach the Sensor Pod. • Clean the skin with alcohol and make sure it is completely dry before you attach the Sensor Pod. Do Not leave any substance on the skin where the Needle inserts. • You may use medical tape (such as Blenderm™) over the white adhesive patch of the Sensor Pod, but Do Not place the tape over the CGM Transmitter or the plastic parts of the Sensor Pod.

Problems with CGM Calibration/Recalibration

Your CGM requires calibration with fingerstick BG values at various times. After entering a BG value(s) into your pump, you may still be prompted to enter another BG value(s).

CGM CALIBRATION ISSUE	SUGGESTED SOLUTION
Repeat prompts to enter BG values during startup calibration	- You must enter 2 separate fingerstick BG values when prompted at the end of the 2-hour startup period. - BG values must be within 2.2–22.2 mmol/L and must have been taken within the last 5 minutes. - You may continue to be reminded to enter another BG value(s) if one or both of the BG values you have entered is/are not accepted. The reminder will re-appear until both BG values are accepted and startup calibration is successful.
Repeat prompts to enter BG values during calibration update/recalibration	- You must enter at least one fingerstick BG value every 12 hours for the calibration update. - BG values must be within 2.2–22.2 mmol/L and must have been taken within the last 5 minutes. - You may continue to be reminded to enter another BG value(s) if the one you entered is not accepted. The reminder will re-appear until the BG value is accepted and calibration update/recalibration is successful.
Continued prompts to enter BG values even after following all instructions	- Your pump and CGM Sensor/Transmitter may not be communicating. Make sure the devices are within RF range. Check to see if the ??? or ANT symbol appears in place of your current CGM reading on the CGM Data or Trend screen. Do Not enter fingerstick BG values for startup calibration or calibration update/recalibration if ??? or ANT appears. Wait 10 minutes to see if the devices start communicating and then enter a new fingerstick BG value. - BG values must be within 2.2–22.2 mmol/L and must have been taken within the last 5 minutes. - If your pump and CGM Sensor/Transmitter are communicating, and you continue to be prompted for additional fingerstick BG values, contact Customer Support or your local Animas distributor (see page 187) for assistance.

Problems with RF communication

Certain conditions may cause RF communication between your pump and CGM Sensor/Transmitter to be lost or interrupted. When RF communication is lost or interrupted, **???** or **ANT** will appear instead of your current CGM reading on the CGM Data and Trend screens. If your pump and CGM Sensor/Transmitter are not within RF range, the Transmitter Out of Range Warning may also display/sound (see page 134). The most common causes for RF communication to be lost or interrupted are listed in the table below, along with some suggested solutions. You will need to wait 10 minutes once RF communication resumes for CGM readings to begin appearing again on your pump.

POSSIBLE CAUSE OF RF COMMUNICATION PROBLEMS	SUGGESTED SOLUTION
Your pump and CGM Sensor/ Transmitter are not within allowable RF range	Make sure your pump and CGM Sensor/Transmitter are within 3.6 meters (12 feet) of each other.
Damp clothing	Change to dry clothing.
Electric blankets	Remove the blanket.
Waterbeds	Switch to regular bed.
Nearby metallic objects	Remove or move away from metallic objects.
High levels of electrical noise	Move away from the source of the noise.

CGM Sensor Failures/Errors

Your CGM session may be interrupted or stopped before the end of a full 7-day period due to CGM Sensor failure or error.

CGM Sensor Failures – The CGM Sensor Failure Warning (see page 135) or CGM Data Failure Warning (see page 137) will display/sound, and the CGM session will stop. Call Customer Support or your local Animas distributor (see page 187) for assistance before inserting a new CGM Sensor and starting a new CGM session.

CGM Sensor Errors – The CGM Sensor Error 0/Error 1 Warning (see page 136) will display/sound. There may be a CGM data gap during the period the CGM Sensor was not functioning properly. CGM Sensor errors may resolve themselves and the CGM session will continue. The CGM Sensor should be replaced if no CGM readings appear after recalibrating.

Follow the guidelines below to have the best result with your CGM Sensors.

POSSIBLE PROBLEMS	SUGGESTED SOLUTION
Expired/damaged CGM Sensors, or CGM Transmitter/Sensor not attached/secured properly	• Do Not use expired CGM Sensors. • Store CGM Sensors at room temperature. See <i>Chapter 1</i> in <i>Section III</i>, pages 141-144 for maintenance and storage of your CGM Sensors. • Make sure your CGM Transmitter is snapped in fully. • Make sure your Sensor Pod is not dislodged or peeling up.

CHAPTER 4 - SICK DAY GUIDELINES

During periods of minor illness*, it may be more difficult to maintain good control of your diabetes. Examples of minor illness are: dental surgery, colds, nausea/vomiting, sore throat, mild infections, diarrhea, fever. However, you should call your health care team if:

- Illness persists without improvement for 24-48 hours.
- Temperature rises above 37.8° Centigrade (100° Fahrenheit).
- Vomiting or diarrhea continues longer than 4 hours.
- There are moderate to large amounts of ketones in urine.
- BG levels continue to run less than 3.3 mmol/L or above 13.9 mmol/L (above 7.2 mmol/L during pregnancy) after taking extra bolus doses as prearranged by your health care team.
- You show signs of ketoacidosis, dehydration or other serious problems such as: increased drowsiness, abdominal or chest pain, difficulty breathing, fruity odor to the breath, dry cracked lips, mouth or tongue.
- Any uncertainty as to what to do to take care of yourself.

Never omit your insulin! If you are ill and cannot eat, your need for insulin continues and may also increase.

- Continue your usual basal dose of insulin along with bolus insulin to cover food eaten or to correct high BG as prearranged with your health care team.
- You may need to temporarily increase or decrease your basal rate by using the Temp Basal feature as prearranged with your health care team.

Medication

Always let your health care team know ALL medications you are taking. Even medications you are taking for other reasons may impact your diabetes management, so it is important that you always let your health care team know all the medications you are taking.

⚠ CONTRAINDICATION: Use of acetaminophen-containing medications while the CGM Sensor is inserted may affect the performance of the CGM.

Blood and Urine Testing

- Check your BG before your usual mealtime and every 2-4 hours if indicated.
- **Test your blood or urine for ketones at least 4 times a day, or according to instructions from your health care team.**

Fluids and Diet

Always follow your health care team's sick day guidelines. Fluid intake is essential with any illness. Consume 240 ml (8.3 ounces) of fluid per hour. Every third hour consume 240 ml (8.3 ounces) of a sodium-rich liquid, such as bouillon. You need to consume 150-200 grams of carbohydrates daily. If ketones are moderate, contact your health care team. Develop a sick plan with your health care team prior to illness.

* Mensing C., The Art and Science of Diabetes Self-Management Education. 2006. Chicago: American Association of Diabetes Educators.

Exercise and Sports

There are many options for wearing your pump during exercise and sports activities. During “low-contact” sport activities, such as walking, biking or aerobics, your pump can be clipped to the waistband, or for added security, placed in a “sport case.” During “contact” sports such as baseball, basketball or hockey, your pump can be disconnected for up to one hour. Always follow your health care team’s individual guidelines when disconnecting your pump because you may need to compensate for missed basal insulin. Before and after you disconnect for any length of time, remember to check your BG levels.

Swimming

Your pump is tested for immersion in water to a depth of 3.6 meters (12 feet) for 24 hours under normal swimming conditions. You should not wear your pump while scuba diving or when using high diving boards. Your pump should not be taken into hot tubs, as the extreme temperature can adversely affect insulin quality.

If your pump has been dropped, examine it carefully for cracks or signs of damage. If the back label of your pump is not securely affixed or if you suspect your pump may have been damaged or otherwise had its waterproof integrity compromised, **Do Not** use in water. Call Customer Support or your local Animas distributor. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).

Your CGM components are tested at IPX8 (resistance to jetting water and continuous submersion of Sensor and Transmitter for 24 hours at a depth of 2.4 meters (8 feet)).

NOTE: CGM readings may not be transmitted from your CGM to the pump while in water.

High Altitude Activities (Skiing, Hiking, etc.)

Your pump is tested at altitudes up to 3048 meters (10,000 feet) at standard operating temperatures. Extreme altitude, temperature or atmospheric conditions may affect pump performance. Refer to page 167 for more information on operating conditions. Your CGM components (and possibly your BG meter) have not been tested in extreme altitudes. Refer to pages 174-175 for more information on operating conditions.

Traveling

With a pump, traveling becomes less complicated and more enjoyable. However, traveling still requires preparation. Remember to order your pump supplies in advance and pack the following items:

- A letter from your health care team that explains the necessity of carrying insulin supplies and wearing a pump.
- A prescription for insulin, both rapid-acting for your pump and the type recommended by your health care team in case you need to take insulin by injection (Remember, your pump is designed and calibrated to use U100 concentration insulin only. Use of any insulin with lesser or greater concentration can result in serious injury or death.)

- Emergency supplies listed in *Before You Begin*, page XV.
- Accessible snacks.
- Bottled water to prevent dehydration while flying. (Remember to check your BG frequently to distinguish between high BG dehydration and normal flight dehydration.)
- The name of a referral health care team at your final destination in case of an emergency.

Also to consider when traveling:

- Pack your insulin carefully so that it is not exposed to extreme temperatures or temperature changes. (Refer to the instructions that came with your insulin for appropriate storage conditions.)
- Pack your pump supplies in carry-on luggage when traveling by air or train. **Do Not** pack your supplies in checked luggage. Contact your local airport administration or security office before traveling by air to obtain prescription/medical supply carry-on regulations.
- Your pump may set off the metal detector at airport security check-in. Additionally, airport security systems, such as X-rays, may damage the pump, so it may be necessary to disconnect and remove the pump prior to going through security. Contact your local airport administration or security office before traveling by air to obtain information about bringing your pump through airport security check-in.
- Delays through customs may occur if you have a pump malfunction and need a pump replacement. Call Customer Support or your local Animas distributor for information about obtaining a pump replacement. In the United Kingdom, call (free phone) 0800 055 6606. In Ireland, call 1 800 812 715. All other countries, call your local Animas distributor (see page 187).
- Adjust your pump's clock when crossing time zones.

For more information on traveling with pumps, visit the American Diabetes Association (ADA) website (www.diabetes.org) or call your local airport for security guidelines that may apply.

Intimacy

Your pump need not interfere with intimacy. You can disconnect most infusion sets. Always follow your health care team's guidelines when disconnecting from your pump. You may need to compensate for missed basal insulin. Also, before and after you disconnect for any length of time, remember to check your BG levels.

CHAPTER 6 - MY INFORMATION

This chapter provides tables to record information needed for programming your personal settings into your pump. Consult your health care team for correct information for your personal treatment plan.

Insulin to Carb Ratios (I:C)

Daily Time Slot	My I:C ratio
12am	

Insulin Sensitivity Factor (ISF)

Time of Day	My ISF
12am	

BG Targets

Time of Day	My BG Target	My BG Target range (+/-)
12am		

Temp Basal Rate Decrease for Activity

Activity Type	% Decrease	Set Temp in advance of activity (yes or no)	Minutes to set in advance
Light (gardening, walking, shopping)			
Moderate (leisurely biking, golf {no cart})			
Strenuous (basketball, jogging, swimming)			
Sustained (ice skating, rowing, hiking)			

My duration for Insulin on Board (IOB) is: _____

Basal Programming Date _____

Segment Start Time	Program 1 Weekday Units/Hr	Program 2 Other Units/Hr	Program 3 Weekend Units/Hr	Program 4 Exercise Units/Hr

Basal Programming **Date** _____

Segment Start Time	Program 1 Weekday	Program 2 Other	Program 3 Weekend	Program 4 Exercise
	_____ Units/Hr	_____ Units/Hr	_____ Units/Hr	_____ Units/Hr

Basal Programming **Date** _____

Segment Start Time	Program 1 Weekday	Program 2 Other	Program 3 Weekend	Program 4 Exercise
	_____ Units/Hr	_____ Units/Hr	_____ Units/Hr	_____ Units/Hr

Basal Programming Date _____

Segment Start Time	Program 1 Weekday	Program 2 Other	Program 3 Weekend	Program 4 Exercise
	Units/Hr	Units/Hr	Units/Hr	Units/Hr

ANIMAS® VIBE™ INSULIN PUMP WARRANTY

Animas® warrants that the Animas® Vibe™ Insulin Pump will be free from defects in material and workmanship, for a period of four (4) years from the date of purchase by the original purchaser. This limited warranty extends only to the original retail purchaser. If an Animas® representative is not available in your area, contact your local Animas distributor (see page 187) for warranty assistance.

If, during the warranty period, the pump should fail because of a defect in material or workmanship, it may be returned to Animas® and Animas® will repair or replace your pump with a new or recertified pump, at Animas®, option, without charge to the purchaser. In certain circumstances and at its sole discretion, Animas® may instead elect to refund all or a portion of the purchase price of the pump to the purchaser. Freight and transportation charges, where applicable, incurred in shipping a pump to be repaired or replaced under this limited warranty will be paid by Animas®. In the event a pump is replaced or repaired under this warranty, the warranty period shall not be extended. Once you have received your repaired or replaced pump, you must return your original pump to Animas®. In the event it is not returned, this warranty shall be void and the user will not be entitled to future pump replacement or repairs.

This limited warranty is valid only if the Animas® Vibe™ Insulin Pump is used under normal use and conditions and in accordance with the manufacturer's instructions as detailed in the Owner's Book provided to you at time of purchase. This limited warranty does not extend to any damage resulting from the following:

- changes or modifications to the pump by the user or any other third person after the date of manufacture;
- service or repairs performed by any person or entity other than an Animas®-authorized service person;
- a force majeure or other event beyond the control of Animas®;
- accidents, negligence, misuse, or abuse of the pump by the user or any other third person, including, but not limited to, improper storage of or physical abuse such as dropping or otherwise damaging the Animas® Vibe™ Insulin Pump; or
- normal "wear and tear," including but not limited to cosmetic damage such as scratched display lenses and/or scratched paint

This limited warranty only covers the pump and does not cover batteries, infusion sets, cartridges, battery caps, or other accessories of the insulin pump.

Except as expressly set forth in this limited warranty, all other warranties are expressly disclaimed and excluded, including, without limitation, any warranties of merchantability or fitness for a particular purpose.

The remedies provided for in this warranty are the exclusive remedies available in the event of any breach hereof. Except for such remedies, Animas®, its suppliers, and its distributors shall not be liable for any losses, liabilities, claims, or damages of any kind or nature whatsoever, including, without limitation, any indirect, consequential, incidental, or special damages caused by or arising from a defect of the insulin pump.

ANIMAS® VIBE™ INSULIN PUMP ACCESSORY WARRANTY

Limited Product Warranty for Insulin Pump Accessories (Cases, Clips, Skins, etc.)

Your Animas® Vibe™ Insulin Pump accessory is warranted against defects in materials and workmanship for a period of THREE (3) MONTHS from the date of original retail purchase. If a defect exists, Animas Corporation, at its option and to the extent permitted by law will (1) repair the product at no charge using new or refurbished parts, (2) exchange the product with a functionally equivalent product that is new or refurbished, or (3) refund the original purchase price. This warranty is available only to the original retail purchaser and excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® IS NOT LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR SERVICE OF THE PRODUCT. THE WARRANTY AND REMEDIES DESCRIBED ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES, AND CONDITIONS, WHETHER ORAL, WRITTEN, EXPRESS, STATUTORY OR IMPLIED. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® DISCLAIMS ALL IMPLIED AND STATUTORY WARRANTIES, INCLUDING, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IF IMPLIED WARRANTIES CANNOT BE DISCLAIMED, THEN SUCH WARRANTIES ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. Any recovery is limited to the original purchase price. No other person is authorized to modify this limited warranty.

ANIMAS® VIBE™ INSULIN PUMP MAINTENANCE PARTS WARRANTY

Limited Product Warranty for Insulin Pump Maintenance Parts (Battery Caps, Cartridge Caps, etc.)

Your Animas® Vibe™ Insulin Pump maintenance part is warranted against defects in materials and workmanship for a period of SIX (6) MONTHS from the date of original retail purchase. If a defect exists, Animas Corporation, at its option and to the extent permitted by law will (1) repair the product at no charge using new or refurbished parts, (2) exchange the product with a functionally equivalent product that is new or refurbished, or (3) refund the original purchase price. This warranty is available only to the original retail purchaser and excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® IS NOT LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR SERVICE OF THE PRODUCT. THE WARRANTY AND REMEDIES DESCRIBED ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES, AND CONDITIONS, WHETHER ORAL, WRITTEN, EXPRESS, STATUTORY OR IMPLIED. TO THE EXTENT PERMITTED BY APPLICABLE LAW ANIMAS® DISCLAIMS ALL IMPLIED AND STATUTORY WARRANTIES, INCLUDING, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IF IMPLIED WARRANTIES CANNOT BE DISCLAIMED, THEN SUCH WARRANTIES ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. Any recovery is limited to the original purchase price. No other person is authorized to modify this limited warranty. Some states do not allow limitations on how long an implied warranty lasts, or exclusions of incidental or consequential damages, so the above limitations may not apply to you. This warranty gives you specific legal rights, and you may have other rights, which vary from state to state.

Technical Specifications – Animas® Vibe™ Insulin Pump

NOTE: When applicable, testing used 23" Comfort™ infusion set and temperature of 23° C ± 1° C (73° F ± 2° F)

Dimensions:	8.26 x 5.08 x 2.18 centimeters (3.25 x 2.00 x 0.86 inches)
Weight:	Approximately 105 grams (70 ounces)
Number of Basal Segments:	12 per Program
Number of Basal Programs:	4
Basal Delivery Frequency (Basal rates of 0.2 U/hr or higher):	every 3 minutes
Temp Basal Range:	-90% to +200%, in 10% increments, OFF
Temp Basal Duration:	0.5 hrs to 24 hrs
Extended Bolus Duration:	0.5 hrs to 12 hrs; 0.5 hr increments
Battery Type:	1.5 Volt Energizer® AA Ultimate (recommended) Lithium or 1.5 Volt AA Alkaline (optional)
Number of Batteries:	1
Battery Life, Typical use:	approximately 3 to 4 weeks for a Lithium Ultimate Battery
Maximum volume infused under single fault condition:	Max 2.0U
Cartridge Capacity up to:	2.0 mL or 200 units
Storage Conditions:	-20° C (-4° F) to +60° C (+140° F) 10% to 100% relative humidity, including condensation 500 Hpa to 1060 Hpa Batteries must be removed during storage periods exceeding 2 weeks.
Operating Conditions:	+5° C (+40° F) to +40° C (+104° F) Outside these temperatures, the flow accuracy and time to occlusion could be compromised. 700 Hpa to 1060 Hpa 20% to 90% relative humidity, including condensation up to 3048 meters (10,000 feet)
Critical Audible Alarms:	50 dB(A) at 1m min., per IEC 60601-2-24.
Pump Disposal:	Contact Animas Corporation or your local Animas distributor (see page 187) for pump disposal information.
Audio Bolus Range:	0.1–2.0U in 0.1U step 0.5–10.0U in 0.5U step 1.0–20.0U in 1.0U step 5.0–35.0U in 5.0U step

Performance Characteristics

Flow Rate Accuracy

Delivery Mode	Accuracy
Bolus	+/- 5%
Basal	+/- 5%

Maximum Time to Occlusion Alarm*

Basal/bolus delivery	Low occlusion sensitivity setting	High occlusion sensitivity setting
0.025 U/Hr basal	120 hours	72 hours
1.0 U/Hr basal	3 hours	1.5 hours
3U or more bolus	30 seconds	8 seconds

*Certain factors, such as the presence of air in the infusion set or the cartridge and/or ambient temperature changes, can delay an occlusion alarm.

Occlusion Pressure Threshold: 15 psi typical, 30 psi max.

Bolus Volume after Occlusion release: • 1.0U max with occlusion sensitivity set to high
(1.0U/Hr basal) • 3.0U max with occlusion sensitivity set to low

Delivery Rates:

- Bolus, under 1U: 1.1 to 2.2U/sec
- Bolus, 1U or more (normal delivery speed): 0.5 to 0.9U/sec
- Bolus, 1U or more (slow delivery speed): 0.2 to 0.4U/sec
- Prime: 1.7 to 3.3U/sec

Insulin Types Used: Rapid-acting U100 insulin or regular (short-acting) U100 insulin

Basal Rate Range: 0.025-25U/Hr in 0.025U/Hr steps

Bolus Range: 0.05-35U in 0.05U steps

Protection from equipment error: More than 1.5 million redundant safety cross-checks per day for both hardware and software functionality.

RF specifications:

- Range between pump and CGM Sensor/Transmitter: 3.6 meters (12 feet)
- Frequency: 2.4 GHz
- Pump Mode: Receive only

Continuous Operation, Internally Powered Device

Type BF Medical Equipment (Patient isolated, not defibrillator protected)

Watertight Equipment, IPX8 (protected against the effects of submersion, tested at 3.6 meters (12 feet) for 24 hours).

Infrared communication port

Electromagnetic Emissions:

The information contained in this section is intended to provide guidance on the proper operation of the Animas® Vibe™ System with respect to electromagnetic compatibility (EMC). Following this guidance will not guarantee faultless operation but should provide reasonable assurance of such. The tables in this section are required by the EMC standard, IEC 60601-1-2.

Medical electrical systems need special precautions regarding electromagnetic compatibility (EMC) and need to be installed and put into service according to the EMC information provided in this Owner's Booklet.

Portable and mobile RF equipment can effect medical electrical systems.

Cables and accessories not specified for use with the Animas® Vibe™ System by Animas® are not authorized. Use of such unauthorized cables or accessories may adversely impact safety, performance and EMC (increased emissions or decreased immunity).

Care should be taken if the Animas® Vibe™ System is adjacent to or stacked upon other electrical equipment. If such use is unavoidable, it should be verified through observation that neither product is affected by the proximate use.

Guidance and Manufacturer's Declaration on Electromagnetic Emissions		
The Animas® Vibe™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Animas® Vibe™ System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Animas® Vibe™ System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Animas® Vibe™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Animas® Vibe™ System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air (pump, IEC 60601-2-24) ± 6 kV contact ± 8 kV air (CGM Transmitter)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Not applicable
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m (pump, IEC 60601-2-24) 3 A/m (CGM Transmitter)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Animas® Vibe™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Animas® Vibe™ System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Animas® Vibe™ Insulin Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Animas® Vibe™ System is used exceeds the applicable RF compliance level above, the Animas® Vibe™ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Animas® Vibe™ System.

^b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Animas® Vibe™ Insulin Pump

The Animas® Vibe™ System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Animas® Vibe™ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Animas® Vibe™ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V1}\right] \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7 \sqrt{P}$
0.01	not applicable	0.035	0.070
0.1	not applicable	0.11	0.22
1	not applicable	0.35	0.70
10	not applicable	1.11	2.2
100	not applicable	3.5	7.0

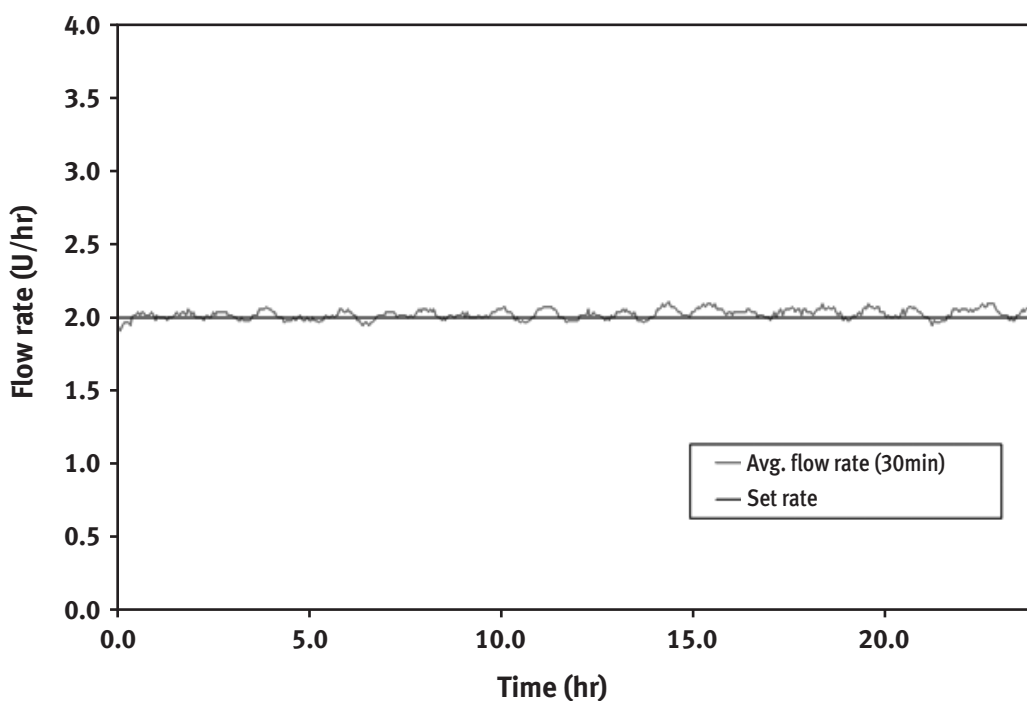
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

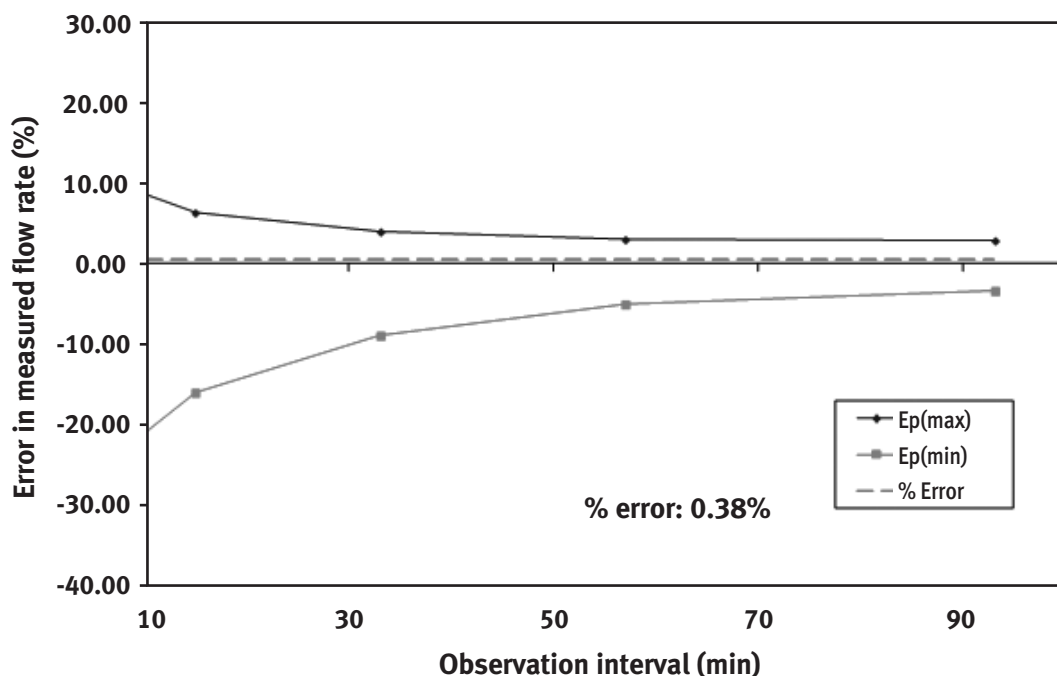
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Pump flow accuracy upon initial start up (per IEC 60601-2-24)

Average flow rate during a 30 minute period. The measurements were taken at an intermediate basal rate of 2.0 U/hr in accordance with 60601-2-24:1998 at room temperature.

**Pump flow accuracy after initial stabilization period (per IEC 60601-2-24)**

The Trumpet curve shows the accuracy of the flow rate during a 5 hour period (300 deliveries) as a function of an averaging window. The reported percent error deviation is calculated from the overall weight increase over the full T_2 time period.



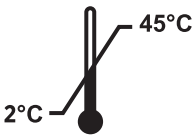
(The above pump flow test indicates that the insulin pump delivered with an accuracy of 0.38%).

Technical Specifications – Dexcom® CGM Sensor and Transmitter

CGM Sensor

Displayed Glucose Range	2.2–22.2 mmol/L (40–400 mg/dL)	
Sensor Life	Up to 7 days	
Calibration	Fingerstick test with commercially-available BG meter	
Calibration Range	2.2–22.2 mmol/L (40–400 mg/dL)	
Operational Conditions	Humidity: Maximum 95 % Relative	 95%
Storage Condition	Room Temperature	
Moisture Protection	IPX 5: water resistance to jetting water IPX 8: continuous submersion to a depth of 2.4 meters (8 feet) for 24 hours	IPX 5 IPX 8
Sterilization	Sterile by electron beam	STERILE R

CGM Transmitter

Dimensions (including Sensor Pod)	Length: 3.8 centimeters (1.5 inches) Width: 2.3 centimeters (0.9 inches) Thickness: 1.3 centimeters (0.5 inches)	
Weight (including Sensor Pod)	10.0 grams (0.4 ounces)	
Communication Range	3.6 meters (12 feet)	
Frequency Range	2.425 – 2.477 GHz	
Power Supply	Silver Oxide Batteries	
Operational Conditions	Temperature: 10°–42° C (50°–108° F) Humidity: Maximum 95% Relative	 95%
Storage Conditions	Temperature: 2°–45° C (36°–113° F)	 45°C 2°C
Limited Warranty	6 months	
Moisture Protection	IPX 5: water resistance to jetting water IPX 8: continuous submersion to a depth of 2.4 meters (8 feet) for 24 hours	IPX 5 IPX 8

Performance Characteristics

PARAMETER	PERFORMANCE CHARACTERISTICS
Frequency Allocation	ISM Band
Transmitter Frequency Range	2.425 – 2.477 GHz
Bandwidth	270.833 kHz
Maximum Output Power	1.25 mW EIRP
Modulation	MSK
Data Rate	50 kbps
Total Packet	224 bits
Transmit Duty Cycle	4.48 ms at each of 4 transmitter frequencies, every 5 minutes
Data Detection Range	3.6 meters (12 feet)

Appendix A: Glossary



APPENDIX A: GLOSSARY

alpha cells - Alpha cells are found in the pancreas. They produce a hormone called glucagon, which raises BG levels.

alternative site (BG) testing - This is when you obtain BG values from somewhere on your body other than your fingertip. **Do Not** use BG values from alternative site testing for CGM calibration.

applicator - See *CGM sensor applicator*.

audio bolus - Your pump has a special feature that lets you deliver a bolus without having to look at the screen display. This feature is convenient if you wear your pump under your clothing. Once you activate and program this feature, you can use the soft rubber button on the right side of your pump to deliver a bolus.

basal rate - The basal rate is the amount of insulin that is continuously delivered by an insulin pump. It is measured in units per hour (U/Hr). The basal rate usually provides about 40% to 60% of the daily total delivery of insulin.

beta cells - Beta cells are found in the pancreas. They produce insulin, which lowers BG levels. In type 1 diabetes mellitus, the beta cells are destroyed, so the body can no longer produce insulin.

blood glucose (BG) levels - BG levels are the measure of how much glucose (sugar) is in the blood. The normal level is about 3.9–6.1 mmol/L.

blood glucose (BG) meter - Any commercially-available BG meter can be used with your Animas® Vibe™ System.

blood glucose (BG value) - A fingerstick blood glucose test result taken with your commercially-available BG meter.

bolus - A bolus is the amount of insulin delivered at one time, usually before a meal or when BG is high.

cannula - A cannula is a small tube that is inserted into the body. Some infusion sets are designed so that only the cannula remains in the body and the needle used for insertion is removed.

calibration - See *CGM calibration*.

CGM calibration - This is when you enter fingerstick BG values into the pump for initial startup period and at least once every 12 hours thereafter. Calibrations are needed for your Animas® Vibe™ System to display continuous glucose readings and trend information. (**Do Not** use alternative site testing for CGM calibration.)

CGM data gaps - This can happen when the pump does not display a CGM reading that is sent from the Transmitter. Symbols may appear instead of a CGM reading to let you know that the pump cannot display a reading.

CGM reading - The continuous glucose monitoring value sent to your pump every 5 minutes.

CGM rise and fall (rate of change) alerts - Alerts based on how fast your CGM readings rise/fall.

CGM safety lock/transmitter key - The Safety Lock keeps the Needle inside the Applicator before you are ready to insert. It also helps you snap the Transmitter out of the Sensor Pod after your CGM session has ended.

CGM sensor applicator - A disposable piece that comes attached to the Sensor Pod, and inserts the Sensor Probe under the skin. There is a Needle inside the Applicator that you remove once you have inserted the Sensor Probe.

CGM sensor pod - The small base of the Sensor attached to your belly that holds the Transmitter and Sensor Probe in place. The Sensor Pod and Transmitter are all that remain on your skin during each CGM Sensor use.

CGM sensor probe - The part of the Sensor that is inserted under your skin with the Applicator. It measures the glucose levels in your surrounding tissue fluid.

CGM startup period - The 2-hour startup period after you tell the pump you have inserted a new Sensor (CGM readings cannot be provided during this time).

CGM components - The Sensor, Transmitter, and other components used to insert/remove the Sensor.

CGM transmitter - The CGM component that snaps into the Sensor Pod and wirelessly sends CGM readings to your pump.

CGM transmitter ID - Transmitter ID/Serial Number that is entered into your pump to talk to the Transmitter.

CGM transmitter latch - The small disposable piece that snaps the Transmitter into the Sensor Pod. It is removed after the Transmitter is snapped in.

CGM trends - Trends let you see the pattern of your glucose levels over time; you can see where your glucose levels have been and where your glucose levels are headed. The pump displays five glucose Trend Graphs: the 1-Hour, 3-Hour, 6-Hour, 12-Hour, and 24-Hour Graphs. Each Trend Graph shows glucose trends over the amount of time shown on the screen.

CGM trend (rate of change) arrows - Arrows on CGM Data and Trend screens that indicate how fast your CGM readings are changing. Seven different arrows show you when your glucose speed and direction change.

combo bolus - Your pump lets you split a bolus amount into 2 parts, a Normal portion and an Extended portion. The Normal portion is delivered all at once and the Extended portion is delivered over an extended period of time that you set. A combo bolus is useful when eating foods that contain carbs that are absorbed more slowly over time.

continuous glucose monitoring (CGM) - The automatic measurement of glucose levels every few minutes using a method/device other than a traditional BG meter.

dawn phenomenon - More insulin may be required in the early morning hours of normal sleep to counteract the release of several hormones that act to increase BG levels. This

increased need for insulin is known as dawn phenomenon and may cause a person with diabetes to have a high BG level in the morning upon waking. Basal rate delivery by the Animas® Vibe™ Insulin Pump can be programmed to compensate for dawn phenomenon.

default - A pump setting that is selected automatically unless another option is chosen.

diabetes - Diabetes is a complex disease in which the body cannot maintain healthy BG levels because either enough insulin cannot be produced or the body cannot appropriately use insulin. In type 1 diabetes, the body no longer produces insulin and in type 2 diabetes, the body cannot use insulin properly.

diabetic ketoacidosis (DKA) - DKA results when there is not enough insulin available to help glucose enter the cells where it is used for energy. The body, in turn, burns muscle and fat for energy. A waste product of fat burning is ketones. Ketones accumulate in the blood and then pass through the urine and lungs. This condition can be identified by urine and/or blood tests. DKA usually requires hospitalization and can be fatal if not promptly treated.

gastroparesis - Gastroparesis is a complication of diabetes that causes delayed emptying of the stomach, resulting in unpredictable swings in BG levels.

gestational diabetes - Gestational diabetes is a form of diabetes that may develop during pregnancy. In some women, certain hormones normally produced by the body during pregnancy can result in high BG levels. If the body cannot produce enough insulin, this can lead to hyperglycemia and may require treatment with insulin. Gestational diabetes usually ends when the baby is born, but many mothers who experience gestational diabetes may later develop Type 2 diabetes.

glucagon - Glucagon is a hormone produced by the alpha cells in the pancreas. It causes BG levels to rise.

glucose - Glucose is a carbohydrate and the body's most important source of energy. It is produced from digested food, by the normal action of the liver, and is carried by the blood and other fluids throughout the body.

hyperglycemia - Hyperglycemia is also known as high blood glucose (BG). It occurs when BG levels rise above 10.0 mmol/L, and the body does not have enough or cannot use insulin to process food. Symptoms of hyperglycemia include nausea, vomiting, muscle and joint aches, blurred vision, excessive thirst, and frequent urination. Over time, weight loss can result. Hyperglycemia can occur even while using an insulin pump and can lead to diabetic ketoacidosis (DKA) if untreated.

hypoglycemia - Hypoglycemia is also known as low blood glucose (BG). It occurs when BG levels drop to below 3.9 mmol/L. This can happen if a person with diabetes has taken too much insulin or has exercised more than usual. Symptoms of hypoglycemia include dizziness, shakiness, rapid heartbeat, sudden hunger, cold or clammy skin, fuzzy vision, confusion, mood changes, and tingling or numbness in the hands, arms, tongue, or lips. Hypoglycemia can occur even while using an insulin pump, and if left untreated, can lead to unconsciousness and diabetic coma.

infrared - Infrared is a wireless means by which the Animas® Vibe™ Insulin Pump communicates with external devices using an optical signal which is invisible to the human eye.

infusion set - An infusion set consists of a length of thin plastic tubing (available in various lengths) with a Luer-lock connector at one end, and at the other end, a very small cannula that is placed under the skin. It is connected to the insulin pump and used to deliver insulin to the body.

infusion site - The infusion site is the place on the body where the infusion set needle is inserted under the skin.

insulin - Insulin is a hormone produced by the beta cells in the pancreas. Insulin is needed by the body to regulate the production and use of glucose.

insulin limits - Insulin limits are a programmable feature of the Animas® Vibe™ Insulin Pump. After consulting with your health care team, you can use the Advanced Setup menu to program maximum limits for basal rate delivery, bolus delivery, 2-hour, and total daily delivery.

insulin on board (IOB) - Refers to how much insulin remains in your body from a previous bolus. Knowing how much insulin remains allows you to adjust your next bolus amount accordingly to avoid delivering too much insulin. You can use the IOB feature on your pump to account for any remaining insulin when calculating suggested bolus amounts.

insulin pump - An insulin pump is a small, battery-powered device that mechanically pumps measured amounts of insulin through an infusion set into the body. THE PUMP IS NOT AUTOMATIC. You program and control it, and you must perform four to six BG tests daily to ensure delivery of appropriate amounts of insulin by the pump.

insulin sensitivity factor (ISF) - Refers to how much you can lower your BG (in mmol/L) with 1 unit of insulin. Your ISF is one of several factors you use in calculating the amount of insulin you should deliver to cover for a high BG. Your pump will use the ISF(s) you have programmed into your pump when calculating suggested bolus amounts.

insulin to carb (I:C) ratio - Refers to how many carbs you can cover with 1 unit of insulin. Your I:C ratio is one of several factors you use in calculating the amount of insulin you should deliver to cover a carb amount. Your pump will use the I:C ratio(s) you have programmed into your pump when calculating suggested bolus amounts.

ketones - Ketones, or ketone bodies, are substances produced by normal liver activity, and used by muscle tissue. In uncontrolled diabetes, the process becomes unbalanced and ketones can accumulate in the blood, pass through the urine and ultimately result in diabetic ketoacidosis (DKA).

Luer-lock - A Luer-lock, or Luer connection, is a standardized, specially threaded fitting used to connect the infusion set to the pump's insulin cartridge.

maximum total daily dose (TDD) delivery warning - You can program your pump to alert you when combined basal and bolus insulin delivery will exceed a maximum daily amount you have set in your pump.

maximum two-hour (2hr) delivery warning - You can program your pump to alert you when combined basal and bolus insulin delivery will exceed a maximum 2-hour amount you have set in your pump.

mmol/L - mmol/L is the unit used to measure glucose levels. It is the abbreviation for millimoles of glucose per liter of blood. To convert mmol/L to mg/dL, divide by 0.055 or multiply by 18.02.

occlusion - Occlusion means “blockage.” The Animas® Vibe™ Insulin Pump is designed to be able to sense when delivery of the insulin is being blocked for some reason. The pump will automatically stop delivering insulin and give an alarm to alert you to clear the occlusion and re-start the pump.

o-ring - Both the cartridge and the battery cap contain an “o” shaped ring made of a soft material that functions as a seal when compressed. O-rings operate properly only if the surface is free of defects (cuts, scratches, abrasion).

radio frequency (RF) - How CGM readings are sent from the Transmitter to the pump.

RF range - The allowable distance between the pump and CGM Sensor/Transmitter for them to be able to communicate.

rise and fall alerts - See *CGM rise and fall alerts*.

pancreas - The pancreas is a glandular organ just behind the stomach, next to the liver. It produces digestive enzymes used to break down proteins in food. It contains alpha cells, which produce glucagon, and beta cells, which produce insulin.

safety lock/transmitter key - See *CGM safety lock/transmitter key*.

sensor pod - See *CGM sensor pod*.

sensor probe - See *CGM sensor probe*.

startup period - See *CGM startup period*.

stress hormones - Stress hormones (or “counter-regulatory” hormones) are released by the body in times of intense physical or emotional stress. These hormones cause the body to release glucose. If the glucose is not used as energy, hyperglycemia and ketoacidosis can result.

subcutaneous - Subcutaneous means beneath the skin. The infusion set needle is placed subcutaneously.

temporary (or temp) basal - Setting a temporary basal lets you increase or decrease your current basal program rate for a desired period of time. Your current basal rate is based on the basal program that is currently active in your pump. When you set a temporary basal, you select a percentage increase or decrease, and then set the desired time period the increase or decrease will stay in effect.

transmitter - See *CGM transmitter*.

transmitter ID - See *CGM transmitter ID*.

transmitter key - See *CGM safety lock/transmitter key*.

transmitter latch - See *CGM transmitter latch*.

trend arrow - See *CGM trend arrow*.

type 1 diabetes - Type 1 diabetes results from destruction of the beta cells in the pancreas. People with type 1 diabetes mellitus must use insulin to regulate their BG levels.

type 2 diabetes - Type 2 diabetes usually occurs in people 40 years or older. People with type 2 diabetes have a progressive loss of beta cells over time. They can sometimes regulate their BG levels by following an individual meal plan, exercising and taking antidiabetic pills. They frequently require insulin for optimal BG control.

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